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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

KPH HEALTHCARE SERVICES, INC., a/k/a KINNEY DRUGS, INC., individually and on behalf of all others similarly situated, Plaintiff, v. BAUSCH HEALTH COMPANIES INC., SALIX PHARMACEUTICALS, LTD., SALIX PHARMACEUTICALS, INC., SANTARUS, INC., ASSERTIO THERAPEUTICS, INC., LUPIN PHARMACEUTICALS, INC., and LUPIN LTD., Defendants.	No. **CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

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Plaintiff KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc. brings this class action, on behalf of itself and all others similarly situated, against Bausch Health Companies Inc. (formerly known as Valeant Pharmaceuticals International, Inc.), Salix Pharmaceuticals, Ltd., Salix Pharmaceuticals, Inc., Santarus, Inc., Assertio Therapeutics, Inc. (formerly known as Depomed, Inc.), Lupin Pharmaceuticals, Inc., and Lupin Ltd. (collectively "Defendants"), based on personal knowledge as to itself and upon information and belief as to all other allegations, and alleges as follows.

I. INTRODUCTION

1. Fair competition would have limited the price of a 30-day supply of diabetes prescription drug Glumetza to less than $55. Defendants instead were able to charge more than $3,000 for the brand version and more than $2,200 for the generic version. This Complaint explains how the Defendants' blatant violation of the federal antitrust law allowed them to charge more than 50 times the competitive price for Glumetza and steal more than $2.8 billion from Glumetza purchasers.

2. Patients with Type 2 diabetes use metformin to prevent and control high blood sugar, helping the body to properly respond to its own naturally produced insulin. A person with Type 2 diabetes who fails to control high blood sugar can develop very serious disabilities, such as kidney damage, blindness, and loss of limbs or sexual function.

3. Prescription metformin has been available as a generic drug since 2002. Defendant Assertio developed an extended-release version of metformin that can alleviate some of the drug's common side effects. Assertio obtained several patents on the extended-release technology and began selling extended-release metformin, marketed under the brand name Glumetza, in 2005. Extended-release mechanisms are very common, however, and Assertio's patents were weak and narrow and could not prevent competition from generic versions of the drug.

4. The effects of generic competition for a brand drug are predictable: sales switch quickly from the brand drug to the generic version. Generic drugs are priced at a fraction of the brand drug price, with prices for the generics falling farther as more generics enter the market, and

purchasers shift swiftly to the generics. Brand manufacturers' profits fall dramatically upon generic entry. Forestalling generic entry, then, is the name of the unlawful game.

5. When Defendant Lupin developed a generic Glumetza, Assertio and its marketing partner, Defendant Santarus, sued Lupin for patent infringement. That lawsuit triggered an automatic prohibition on Lupin's entry into the market for 30 months. Just before the 30 months were over and Lupin would enter the market with generic Glumetza, Assertio/Santarus and Lupin settled the patent lawsuit.

6. Assertio/Santarus paid Lupin to delay generic entry. The companies settled the patent litigation in February 2012 with a "reverse payment," that is, a payment from the plaintiffs in the patent lawsuit, Assertio/Santarus, to the defendant in the patent lawsuit, Lupin. Lupin agreed to stay out of the market from 2012 to February 2016. In exchange, Assertio/Santarus agreed that, when Lupin finally did enter the market in 2016, for at least six months they would not compete against Lupin by marketing their own generic version of Glumetza.

7. Those Defendants allocated the Glumetza market between them: Assertio/Santarus got the entire market from 2012 to February 2016, and Lupin got the generic sector of the market from February 2016 until at least August 2016. That market-allocation agreement is blatantly unlawful under antitrust law.

8. Other generic manufacturers could have upended the Assertio/Santarus/Lupin anticompetitive scheme. The Assertio patents' weakness created the risk that another manufacturer could avoid them and market a generic Glumetza before February 2016. To prevent that possibility, Assertio/Santarus and Lupin included in their agreement two deterrent provisions aimed at other competitors: (a) if another generic manufacturer succeeded in entering the market before February 2016, Lupin could also enter on that earlier date; and (b) Assertio/Santarus would not grant a license to any other manufacturer to enter the market sooner than 180 days after Lupin.

9. These deterrents ensured that, no matter how many resources another manufacturer might expend in overcoming Assertio's patents, it could never get the financial reward of being the only generic manufacturer on the market. It could not get that reward by winning a patent lawsuit against Assertio/Santarus—the deterrent provision would allow Lupin to enter earlier; it could not

get that reward by negotiating an earlier-entry license from Assertio/Santarus—the deterrent expressly prohibited such a license.

10. Assertio/Santarus and Lupin unlawfully closed every pathway to generic competition before February 2016. Lupin agreed not to enter before then, and the deterrents eliminated the incentive for other generic manufacturers to try to enter before then. And those Defendants extended the anticompetitive effect beyond February 2016—Assertio/Santarus agreed that they would not compete in the generic sector from February 2016 until at least August 2016 and agreed not to grant a license to any other generic to compete during that time.

11. In short, Assertio/Santarus and Lupin conjured a monopoly in the sale of Glumetza and its generic equivalents where monopoly shouldn't—and wouldn't—have existed under lawful, competitive practices.

12. That monopoly was extremely valuable, and Assertio/Santarus wasted no time in exploiting it. In November 2013, Santarus announced that it was being acquired by Defendant Salix for $2.6 billion. At the time, Glumetza accounted for just under half of Santarus' sales. From 2012 to 2015 Assertio/Santarus and Salix raised Glumetza prices by more than 40%, far outstripping the 4.2% rise in the Consumer Price Index.

13. In April 2015, when Glumetza accounted for more than 25% of its sales, Salix in turn sold the Glumetza monopoly to Valeant Pharmaceuticals, Inc. (now known as Bausch Health). Valeant paid $14.5 billion to acquire Salix.

14. Valeant was known in the industry as a ruthless and remorseless exploiter of drug-product monopolies. As Forbes magazine later characterized it, Valeant's business strategy "emphasized boosting drug prices, gutting research and development budgets, [and] firing employees…." Nathan Vardi & Antoine Gara, *Valeant Pharmaceuticals' Prescription for Disaster*, Forbes, April 13, 2016, https://www.forbes.com/sites/nathanvardi/2016/04/13/valeant-pharmaceuticals-prescription-for-disaster/#6f4f657f206c. "[S]cientists were seen as unnecessary costs to be cut," while Valeant's "drug-price increases became legendary." Industry observers concluded that "Valeant was the pure expression of the view that companies are there to make money for shareholders, every other consideration be damned." Bethany McLean, *The Valeant*

Meltdown and Wall Street's Major Drug Problem, Vanity Fair, Summer 2016, https://www.vanityfair.com/news/2016/06/the-valeant-meltdown-and-wall-streets-major-drug-problem.

15. Within four months of acquiring the Glumetza monopoly, Valeant *raised the price an additional 750%*. The price of a 30-day supply skyrocketed from $350 to more than $3,000. In the half year before the price hike, Salix made $145 million on Glumetza; in the half year after, Valeant made more than $800 million.

16. Piling injury on injury, the unlawful agreements also resulted in an outrageously high price for the generic product when Lupin finally entered the market in February 2016. Valeant complied with the unlawful agreement not to compete in the generic sector, and Lupin took full advantage. With no competition in the generic sector and branded Glumetza being sold at an astronomically high price, Lupin sold a 30-day supply of *generic* Glumetza for more than $2,200. Lupin made more than $650 million in profits on generic Glumetza in 2016 alone.

17. Defendants' anticompetitive scheme has already caused direct purchasers to overpay by more than $2.8 billion. And the scheme continues to reverberate, causing more than $175 million in additional overcharges to direct purchasers every year.

18. On behalf of itself and all other direct purchasers of brand and generic Glumetza, Plaintiff brings this lawsuit to recover damages for overcharges they have already suffered and obtain equitable relief to put a stop to the ongoing harm.

II. INTRADISTRICT ASSIGNMENT

19. Pursuant to Local Rule 3-2(c), this is an Antitrust Class Action to be assigned on a district-wide basis.

III. PARTIES

20. Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. ("KPH") is a corporation organized under the laws of the state of New York, with headquarters in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. KPH is the assignee of McKesson Corporation, who directly purchased branded and

generic Glumetza from Defendants during the Class Period. As a result of Defendants' alleged anticompetitive conduct, KPH paid supracompetitive prices for its Glumetza purchases, and KPH was injured by the illegal conduct alleged herein.

21. Defendant Assertio Therapeutics, Inc. ("Assertio") is a corporation organized under the laws of Delaware with its principal place of business located at 100 South Saunders Road, Suite 300, Lake Forest, Illinois. Until August 14, 2018, Assertio was named Depomed, Inc., which was a party to the unlawful agreements alleged herein. Assertio is the owner or licensee of the relevant patents.

22. Defendant Santarus, Inc. ("Santarus") is a corporation organized under the laws of Delaware and, during much of the relevant time, had its principal place of business in San Diego, California. Its current principal place of business is located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Pursuant to a Commercialization Agreement signed in August 2011, Assertio granted Santarus exclusive rights to manufacture and commercialize Glumetza in the United States. Santarus was a party to the unlawful agreements alleged herein. On January 2, 2014, Santarus was acquired by defendant Salix Pharmaceuticals, Ltd. and became a wholly owned subsidiary of Salix Pharmaceuticals, Inc.

23. Defendant Salix Pharmaceuticals, Inc. is a corporation organized under the laws of California with its principal place of business located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Salix Pharmaceuticals, Inc. joined and adhered to the unlawful agreements alleged herein. Salix Pharmaceuticals, Inc. is a wholly owned subsidiary of Salix Pharmaceuticals, Ltd.

24. Defendant Salix Pharmaceuticals, Ltd. is a corporation organized under the laws of Delaware with its principal place of business located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Effective January 1, 2014, Salix Pharmaceuticals, Inc. and Salix Pharmaceuticals, Ltd. ("Salix") assumed Santarus's rights and obligations under its Commercialization Agreement with Assertio. Salix Pharmaceuticals, Ltd. joined and adhered to the unlawful agreements alleged herein.

25. On April 1, 2015, Salix was acquired by Valeant Pharmaceuticals International, Inc., which, on or about that date, assumed Santarus's and Salix's rights and obligations under the Commercialization Agreement with Assertio. Valeant Pharmaceuticals International, Inc. joined and adhered to the unlawful agreements alleged herein. Effective on July 13, 2018, Valeant Pharmaceuticals International, Inc. changed its corporate name to Bausch Health Companies Inc. Salix Pharmaceuticals, Ltd. is now a wholly owned subsidiary of Bausch Health Companies Inc.

26. Defendant Bausch Health Companies Inc. ("Bausch") is a corporation organized and existing under the laws of British Columbia, Canada with its U.S. headquarters located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Bausch joined and adhered to the unlawful agreements alleged herein.

27. Except where otherwise noted, Defendants Santarus, Salix, and Bausch are collectively referred to herein as "Valeant."

28. Defendant Lupin Pharmaceuticals, Inc. is a corporation organized under the laws of Virginia with its principal place of business located at Harbor Place Tower, 111 South Calvert Street, 21st floor, Baltimore, Maryland 21202. Lupin Pharmaceuticals is a wholly owned subsidiary of Defendant Lupin Ltd. and was a party to the unlawful agreements alleged herein.

29. Defendant Lupin Ltd. is a company organized under the laws of India with its principal place of business located at B/4 Laxami Towers, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400051, India and was a party to the unlawful agreements alleged herein.

30. Lupin Pharmaceuticals, Inc. and Lupin Ltd. are collectively referred to herein as "Lupin."

31. All of the Defendants' wrongful actions described in this Complaint are part of, and in furtherance of, the unlawful restraints of trade alleged herein, and were authorized, ordered, and/or undertaken by the Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the Defendants.

IV. JURISDICTION AND VENUE

32. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a), 26. The action seeks to recover treble damages, interest, costs of suit, equitable relief, and reasonable attorneys' fees for the overcharges paid by the Plaintiff and members of the Class resulting from Defendants' restraints of trade and conspiracy to monopolize and to restrain trade in the sale of Glumetza and its generic equivalents.

33. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 (federal question), 1332 (diversity due to a qualifying class action), 1337(a) (antitrust), and 15 U.S.C. § 15 (antitrust).

34. Venue is appropriate in this district under 15 U.S.C. § 15(a) (Clayton Act), 15 U.S.C. § 22 (nationwide venue for antitrust matters), and 28 U.S.C. § 1391(b) (general venue provision). Defendants transact business within this district, and the Defendants transact their affairs and carry out interstate trade and commerce, in substantial part, in this district.

35. The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of causing injury to, persons residing in, located in, or doing business throughout the United States, including in this district.

V. REGULATORY AND ECONOMIC BACKGROUND

A. Regulatory Structure for Approval and Substitution of Generic Drugs

36. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a manufacturer that creates a new drug must file a New Drug Application ("NDA") in order to obtain approval from the Food and Drug Administration ("FDA") to sell it. 21 U.S.C. §§ 301-392. A NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a) & (b).

37. With the filing of the NDA (and through amendments as necessary during the approval process), the manufacturer must inform the FDA of any patents that the manufacturer alleges "could reasonably be asserted" against a generic manufacturer that makes, uses, or sells a

generic version of the brand drug before the listed patents expire. The FDA will then list these patents in its *Approved Drug Products with Therapeutic Equivalence Evaluations* publication, known as the "Orange Book." Information about any later issued patent that the manufacturer alleges "could reasonably be asserted" against a generic manufacturer must be provided to the FDA within 30 days of issuance of the patent; the FDA then publishes the patent in the Orange Book. 21 U.S.C. § 355(b)(1) & (c)(2).

38. The FDA relies completely on the brand manufacturer's truthfulness about a patent's validity and applicability; the FDA has neither the authority nor the resources to check the manufacturer's representations for accuracy or trustworthiness.

1. Hatch-Waxman Amendments

39. The Hatch-Waxman Amendments to the FDCA, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA and must further show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and that it is bioequivalent, *i.e.*, absorbed at the same rate and to the same extent as the brand. 21 U.S.C. § 355(j)(8)(B). The FDA assigns generics that meet these criteria relative to their brand counterparts an "AB" rating, meaning the generics are therapeutically equivalent to and may be substituted for the brand (as well as other AB-rated generics of the brand).

40. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

41. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches and ushering in an era of historic high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenues for brands and generics totaled $21.6 billion; by 2013, total prescription drug revenues had climbed to more than $329.2 billion, with generics accounting for 86% of prescriptions. *See* IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the U.S. in 2013*, at 30, 51 (Apr. 2014). Generics are now dispensed 95% of the time when a generic version of the drug is available. *Id.* at 51.

2. ANDA Paragraph IV Certifications

42. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications for each patent the brand manufacturer has listed in the Orange Book as claiming the brand product. The generic manufacturer must certify that:

a. no patent has been filed with the FDA (a "paragraph I certification");

b. the patent has expired (a "paragraph II certification");

c. the patent will expire on a particular date and the manufacturer does not seek to market its generic before that date (a "paragraph III certification"); or

d. the patent is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii).

43. If a generic manufacturer files a paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the paragraph IV certification, the FDA cannot grant final approval to the ANDA until the earlier of (i) the passage of 30 months, or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA (referred to as a "30-month stay"). 21 U.S.C. § 355(j)(5)(B)(iii). Before that time, the FDA may

grant "tentative approval," meaning all other scientific and regulatory requirements have been met and the application is approvable save for the 30-month stay/pending litigation. It cannot, however, authorize the generic manufacturer to market its product (*i.e.*, grant final approval), until one of the two conditions is met.

44. The high profit margins on brand drugs and the predictable effects of generic entry—sales switch quickly from the brand to the generic—create powerful financial incentives for brand manufacturers to sue any generic competitor that files an ANDA with a paragraph IV certification, even if the competitor's product does not actually infringe the listed patent(s) and/or the patent is invalid and unenforceable. Simply by listing the patents in the Orange Book and filing the lawsuit the brand manufacturer can delay final FDA approval of an ANDA for up to 30 months.

3. ANDA Exclusivity Period

45. Generics may be classified as (i) first-filer generics, (ii) later-filer generics, or (iii) authorized generics.

46. As an incentive for manufacturers to seek approval of generic alternatives to brand drugs, the Hatch-Waxman Amendments provide that the first manufacturer to file an ANDA containing a paragraph IV certification (the "first filer") gets a period of protection from competition from other generic versions of the drug approved through the ANDA process ("ANDA Exclusivity"). That is, subject to certain limitations the FDA is precluded from approving any other generic version of the product through the ANDA process until 180 days after the first filer enters the market. 21 U.S.C. § 355(j)(5)(B)(iv) & (D).

47. By creating a statutory mechanism to enable early infringement litigation following paragraph IV certifications, the Hatch-Waxman Amendments encourage generic manufacturers to test the validity of pharmaceutical patents and invent around them. The notion is that *bona fide* litigation will result in rulings that either confirm legitimate patent protection or ferret out invalid, unenforceable, or narrow drug patents.

48. As a statistical matter, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, it is more likely that a challenged patent will be found invalid or not

infringed than upheld. For example, an empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009—when the relevant patent case here was filed—reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time. John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1787 (2014) ("[P]atentees won only 164 of the 636 definitive merits rulings, or 26%," and "that number is essentially unchanged" from a decade ago.).

49. An applicant that is otherwise eligible for the 180-day ANDA Exclusivity can forfeit it. As relevant here, a first filer forfeits its 180-day ANDA Exclusivity under the "failure to market" provision if it fails to market its generic drug within 75 days after another manufacturer obtains a final decision that the brand manufacturer's patents are invalid or not infringed. 21 U.S.C. 355 § (j)(5)(D)(i)(I)(bb).

50. The Hatch-Waxman Amendments thereby created a statutory mechanism to enable generic manufacturers that were not the first to file a paragraph IV certification ("later filers") to enter the market before the first filer, despite its 180-day ANDA Exclusivity. The Hatch-Waxman Amendments thus created incentives for later filers to try to enter the market before a first filer that, for example, settled its patent litigation by accepting a delayed entry date (see Section VF below).

B. Competitive Effects of AB-rated Generic Competition

51. AB-rated generics contain the same active ingredient(s) and are determined by the FDA to be just as safe and effective as their brand counterparts. The only material difference between generics and their corresponding brand version is their price. Because generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a brand product and its generic version, or between generic versions of the same drug, is price. Typically, generics are at least 10% to 20% less expensive than their brand counterparts when there is a single generic competitor. This discount typically increases to 48% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the marketing of a generic usually results in significant cost savings for all drug purchasers.

52. Since passage of the Hatch-Waxman Amendments, every State has adopted "generic substitution" laws that either require or permit pharmacies to substitute AB-rated generic equivalents

for branded prescriptions (unless the prescribing doctor has specifically ordered otherwise). As a result of generic substitution laws and other institutional features of the pharmaceutical marketplace, the marketing of AB-rated generics results both in rapid price decline and rapid shift of unit sales from the brand to the generic product. Once a generic equivalent enters the marketplace, the generic quickly captures sales of the branded drug, often garnering 80% or more of unit sales within the first six months. The FTC found that on average, within a year of generic entry, generics had captured 90% of brand unit sales and (with multiple generics on the market) prices had dropped 85%. *See* FTC Staff Study, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 2010) ("FTC Staff Study"), http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

53. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generics in the market goes from one to two. While the availability of just one generic may result in a near-term retail price of a the generic of 10% to 20% less than the brand, the entry of a second generic competitor typically results in near-term retail price reduction of about 48% off the brand price.

54. Brand manufacturers are well aware of the generics' rapid erosion of their sales. Brand manufacturers thus seek to extend their exclusivity for as long as possible, sometimes resorting to unlawful means.

C. Price Competition from Authorized Generics

55. The brand manufacturer has the right to sell a generic version of its own brand product, a so-called "authorized generic." An authorized generic is essentially the brand product, manufactured and marketed under the authority of the brand manufacturer's FDA-approved NDA, but sold in different—generic—packaging. A brand manufacturer does not need to file an ANDA, or obtain any additional FDA approvals, to market a chemically identical generic version of a drug for which it has received approval through the NDA process.

56. A product marketed as an authorized generic—whether marketed by the brand manufacturer itself or by its licensee—is not subject to the first filer's ANDA Exclusivity. The first filer's ANDA Exclusivity is effective against only other products marketed pursuant to an approved

ANDA, not one marketed pursuant to an approved NDA. Thus, a brand manufacturer (or its licensee) may market and sell the authorized generic during the first filer's 180 ANDA Exclusivity.

57. Brand manufacturers price their authorized generics like other generics and compete on price with other generics. Entry of an authorized generic during the ANDA Exclusivity period can mean generic prices drop immediately to half the price of the brand or less, resulting in substantial savings for purchasers. But even at lower prices, the brand manufacturer profits by keeping a portion of the generic market.

58. In fact, brand manufacturers can better compete by pre-selling authorized generics a few months *before* the first filer ANDA generic enters the marketplace, in order to secure multi-year purchase contracts with direct purchasers and "load the generic pipeline" at the expense of the first-filer generic.

59. One study notes that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'" Kevin A. Hassett & Robert J. Shapiro, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals* at 3, Sonecon (May 2007). Another study gives three examples of authorized generics, finding that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand." Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 Health Affairs, n. 3, at 796 (May/June 2007).

60. The FTC estimates that a brand manufacturer whose product faces generic competition increases its overall revenues by as much as 21% when it introduces an authorized generic. FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* 62 (Aug. 2011), https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission.

61. The generic manufacturers' trade association reported to Congress that in a three-year period (before some unscrupulous manufacturers started unlawfully agreeing not to compete with authorized generics) "the brands have launched an authorized generic during every 180-day generic exclusivity period." GPhA Letter to Senate Special Committee on Aging at 5 (Jul. 27, 2006).

62. As a result, a competitive pharmaceutical marketplace includes authorized generic entry during the 180-day ANDA Exclusivity period. While the first ANDA filer enjoys the exclusive right to sell the only ANDA-approved generic product during these six months, the prices at which it can do so are lowered by price competition from authorized generics. Drug purchasers are intended to, and do indeed, benefit from lower prices resulting from authorized generic entry during and after the 180-day ANDA Exclusivity period.

D. Manufacturers' Motive to Conspire

63. In the absence of generic competition, brand manufacturers can usually sell the brand drug far above the marginal cost of production, generating profit margins in excess of 70% (and sometimes up to 98%) while making hundreds of millions of dollars in sales. The ability to make those kinds of profit margins is what economists call market power. When generics enter the market, however, they quickly take 90% or more of the unit sales. And when multiple generics are in the market, competition between them drives their prices to near the marginal cost of production. This competition delivers enormous savings to drug purchasers.

64. The brand and generic manufacturers have a collective interest in preventing or forestalling this competition. If they work together to prevent or delay competition, they can keep the profit margins on all of the unit sales at 70% and split the resulting excess profits among themselves. They can keep for themselves the enormous savings that competition would have delivered to drug purchasers. The following series of charts demonstrates the manufacturers' collective interest in delaying competition.

65. A brand manufacturer in a marketplace without competition from generics gets all of the profits on all of the unit sales:

66. When generic entry occurs, the brand manufacturer loses most of the unit sales; the generic manufacturers sell most of the units, but at drastically reduced prices; and competition delivers enormous savings to consumers.

67. Competition converts what formerly were excess profits into purchaser savings:

68. To avoid this loss of profits, the brand and generic manufacturer can agree not to compete and instead split the purchaser savings between themselves. For such an anticompetitive scheme to work, the brand and generic manufacturers need a way to divide the purchaser savings between themselves. The generic manufacturer will not refrain from competing if it does not share in the ill-gotten gains. Pay-offs from the brand manufacturer are a means by which the brand and generic manufacturers divide between themselves the ill-gotten gains that the delayed competition makes possible. These unlawful pay-off deals are often referred to as "pay-for-delay," "reverse payment," or "exclusion payment" agreements. They are depicted here:

69. It is often necessary for the brand manufacturer to pay off only the first filer (the first generic manufacturer that included a paragraph IV certification in its ANDA). The first filer's agreement to delay marketing its drug may also prevent other generic manufacturers from marketing theirs. If the first filer is eligible for 180-days of ANDA Exclusivity, and does not forfeit it, no other generic manufacturer can enter the marketplace until the end of the ANDA Exclusivity period. In

that circumstance, the brand manufacturer needs to pay off only the first filer in order to delay *all* generic competition.

E. No-AG Payments

70. When some brand manufacturers made unlawful pay-offs to generic competitors in the 1990s, the pay-offs took the form of cash payments. As a result of regulatory scrutiny, congressional investigations, and class action lawsuits, brand and generic manufacturers making and receiving pay-offs got more sophisticated and have tried to hide them in increasingly elaborate agreements.

71. One form of pay-off is a no-authorized generic clause ("No-AG Payment"). Pursuant to a No-AG Payment, the brand manufacturer agrees not to market an authorized generic version of the drug until after a period of time—often 180 days, but sometimes even longer—following the first filer's entry into the market. In exchange, the generic manufacturer agrees to delay entering into the market to compete against the branded drug. Each competitor reciprocally, *i.e.*, mutually, agrees to restrict its competition against the other.

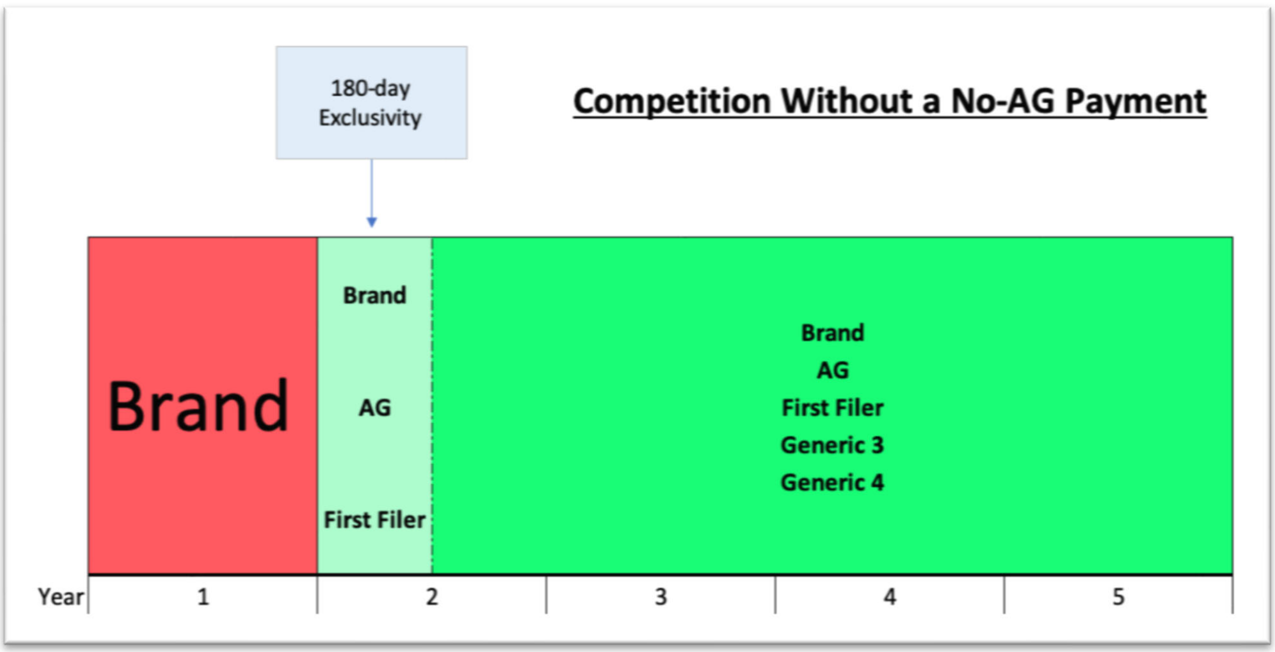
72. As noted in detail above, the generic first filer's 180-day ANDA Exclusivity does not prohibit the brand manufacturer from marketing its *NDA-based* authorized generic during the 180 days. The Hatch-Waxman Amendments' 180-day marketing period is "exclusive" only as against other ANDA-based products, not as against the brand manufacturer's NDA-based authorized generic.

73. As also noted above, absent the No-AG Payment it almost always is financially advantageous for the brand manufacturer to begin marketing an authorized generic as soon as (or weeks or months before) the first generic manufacturer enters the marketplace.

74. Competition from an authorized generic has a drastically negative effect on the generic first filer's revenue, typically cutting it by more than half. The competing authorized generic takes a substantial volume of the unit sales and drives prices lower—all to the benefit of drug purchasers.

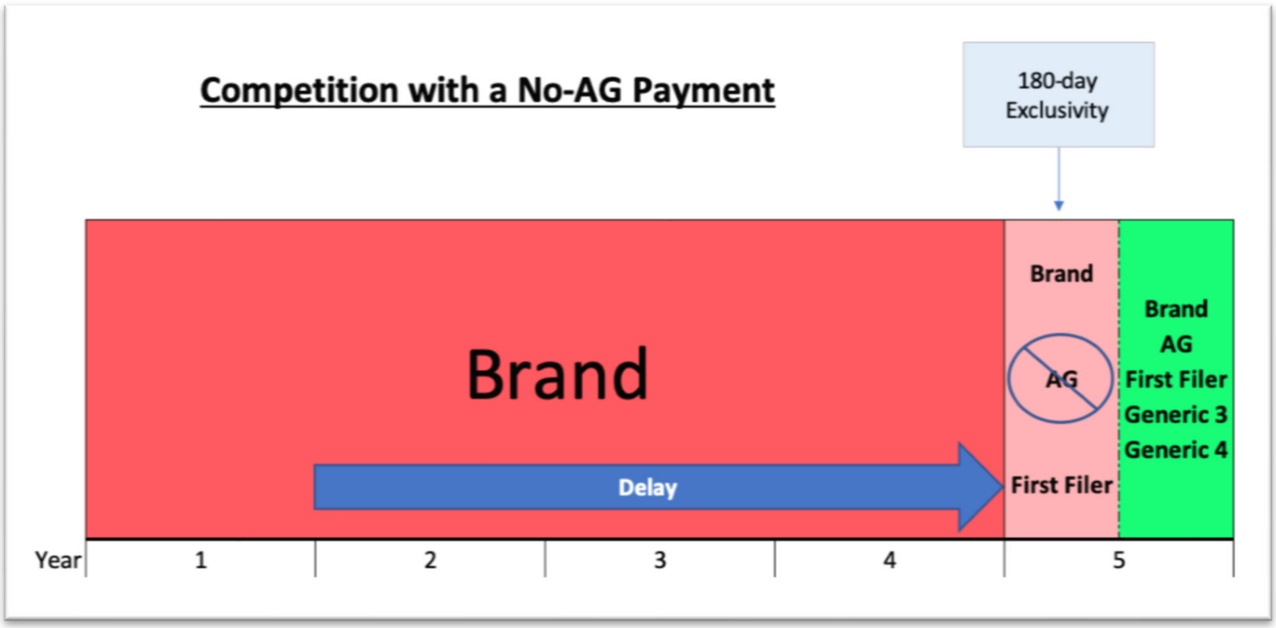
75. In exchange for an agreement from the brand manufacturer not to market an authorized generic that would cause this substantial loss of revenue and profit, a generic first filer may be willing to agree to delay its entry into the marketplace. The additional profits that the brand manufacturer gains from the delayed onset of generic competition more than make up for the profits that it forgoes by not competing with an authorized generic.

76. The state of lawful, fair competition is depicted here:



77. In this example, the brand product is alone in the market for one year (the red area); then three products—the brand product, the authorized generic, and the first filer's generic—are in the market during the 180-day ANDA Exclusivity period (the light green area); then after the 180-day ANDA Exclusivity period two more generics enter the market (the dark green area).

78. Contrast this to the state of competition with a No-AG Payment:



79. In exchange for the No-AG Payment, the first filer agrees to delay entry into the market (the dark red area has grown from one year to four); then during the ANDA Exclusivity period (the light red area) only two products, rather than three, are in the market; and the delayed beginning of the first filer's ANDA Exclusivity period has delayed the entry by all other generics (the dark green area begins in year five instead of year two).

80. The brand manufacturer gains from the delayed onset of generic competition. The first filer gains from the absence of generic competition after it finally does enter the market. And drug purchasers lose three times over: first by the delay in the onset of the first filer's entry into the market; second, by the absence of authorized-generic competition once the first filer finally enters; and third, by the "bottleneck" that the first filer's delayed entry causes—absent forfeiture of the first filer's ANDA Exclusivity, later-filing generic manufacturers cannot enter the market until the expiration of the first filer's artificially delayed ANDA Exclusivity period.

1. No-AG Payment's Value to the Generic Manufacturer

81. A No-AG Payment is very valuable to the first filer. The first filer often earns the overwhelming portion of all of the profits it will ever make on the drug—as much as 80% of all that it will ever make—during the 180-day period. It is almost always more lucrative for the first filer to

have 180 days on the market as the only generic, than to enter the market earlier and compete against an authorized generic. That is why the first filer may be willing to agree to later entry in exchange for a No-AG Payment.

82. The Supreme Court has recognized that 180 days of generic exclusivity "can prove valuable, possibly 'worth several hundred million dollars'" to the first filer. *FTC v. Actavis, Inc.*, 570 U.S. 136, 143 (2013) (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)). And because an authorized generic can reduce the value of that exclusivity by 50% on average, a "no-AG agreement . . . may be of great value to . . . the first-filing generic." *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 404 (3d Cir. 2015).

83. Thus, "no-AG agreements are likely to present the same types of problems as reverse payments of cash." *King Drug*, 791 F.3d at 404. As explained by the then-Chairman of the FTC:

> Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, "if you go away for several years, I'll give you $200 million." Now, the brand might say to the generic, "if I launch an AG, you will be penalized $200 million, so why don't you go away for a few years and I won't launch an AG."

Statement of Chairman Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics (June 2009), http://www.ftc.gov/os/2009/06/P062105authgenstatementLeibowitz.pdf.

84. Pay-offs by means of No-AG Payments usually exceed the value that the first filer could have obtained *even if it had won* the patent infringement litigation. As a reward for winning the patent litigation, the Hatch-Waxman Amendments provide the first filer a period of 180 days of ANDA Exclusivity. But the statute does not prevent the brand manufacturer from marketing an authorized generic during that time. By settling the patent case in exchange for a No-AG Payment, the first filer converts that six months into a period of total generic exclusivity, thus doubling its unit sales while making them at a vastly higher price.

2. No-AG Payment's Value to the Brand Manufacturer

85. While No-AG Payments are very valuable to the generic manufacturer, they would be very costly to the brand manufacturer if they did not have the intended anticompetitive effect of delaying generic entry. The brand manufacturer forgoes making half or more of the generic sales during the 180-day ANDA Exclusivity period. And those forgone sales are a pure loss to the brand manufacturer because the addition of a second generic to the market does not significantly increase the rate at which purchasers substitute a generic for the branded product.

86. Of course, No-AG Payments are exceedingly valuable to the brand manufacturer—despite the loss of sales of an authorized generic—because they do in fact have the intended effect of causing the generic manufacturer to delay entering the market. Standard industry economics establish that the value to a brand manufacturer of a four-year delay in generic entry for a brand drug with $200 million in annual sales is more than $575 million.

F. Deterrents to Later Filers

87. A brand manufacturer can also pay off the generic manufacturer by including in the agreement deterrent provisions designed to prevent other generic manufacturers (*i.e.*, later filers) from entering the market before the delayed entry date to which the first filer has agreed. Two types of these deterrents are Most Favored Entry clauses ("MFE") and Most Favored Entry Plus clauses ("MFEP").

1. Most-Favored-Entry Clauses

88. A typical MFE provides that the first filer will delay entering the market until, say, four years in the future; but if any other generic manufacturer (*i.e.*, a later filer) succeeds in entering the market before that date, the first filer's entry date is also moved up to that earlier date.

89. The purpose and effect of MFEs is to delay generic entry. They dramatically reduce later filers' incentives to try to enter the market before the first filer. Absent the MFEs, a later filer would have a possibility of entering the market before the first filer, thereby enjoying a substantial period with the only ANDA-based generic product on the market.

90. When a later filer gets a final court decision that the brand manufacturer's patents are invalid or not infringed, the first filer forfeits its ANDA Exclusivity if it does not enter the market within 75 days of the court decision. 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb). The first filer would forfeit the statutory exclusivity, for example, if it agreed to delay entry until Year 4 and a later filer got a final court decision of patent invalidity in Year 2. Having agreed not to begin marketing until Year 4, the first filer could not enter the market within 75 days of the later filer's favorable court decision in Year 2. So, the first filer would forfeit its ANDA Exclusivity.

91. An MFE allows the brand manufacturer and the first filer, through their joint conduct, to circumvent the statutory incentive for later filers to try to improve on the entry date to which the first filer agreed. Absent an MFE, the Hatch-Waxman Amendments would allow the later filer to enter in Year 2 and get a substantial period as the only ANDA product in the generics sector of the market. The first filer would be stuck on the sidelines while the later filer was the only ANDA product on the market. The prospect of being the only ANDA product motivates a later filer to incur the substantial costs and burdens of trying to enter the market before the entry date to which the first filer agreed. An MFE eliminates that possibility, deterring later filers from trying to improve on the entry date to which the first filer agreed.

92. MFEs thereby result in delayed generic entry in at least two ways: (i) they deter later filers from trying to gain entry before the first filer, and (ii) by eliminating the threat to the first filer's potential period of exclusivity, they compensate the first filer for delaying its entry into the market. In short, MFEs eliminate later filers' competitive threat to the first filer, in return for which the first filer agrees to later entry than it otherwise would.

93. The Chairman and CEO of Apotex, Inc.—one of the largest generic manufacturers in the world—testified to Congress that MFEs "eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry." The provisions deter others from entering earlier and cause the first filer to accept a later entry date:

> [N]o subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. *Consumers are the biggest losers under this system.* If subsequent filers do not have the incentive to take on the cost of multimillion patent challenges these challenges will not occur. Weak patents that should be knocked out will remain in place, unduly blocking

> consumer access to generics. The challenges to brand patents by generic companies that Hatch-Waxman was designed to generate will decrease. And settlements that delay consumer access to the generic will, in turn, increase.

Statement of Bernard Sherman, CEO, Apotex, Inc., http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg67822/pdf/CHRG-111hhrg67822.pdf at 218 (March 31, 2009).

2. Most-Favored-Entry-Plus Clauses

94. An unscrupulous brand manufacturer could also use another type of later-filer deterrent to compensate the first filer for agreeing to delay entry into the market. A Most-Favored-Entry-*Plus* clause ("MFEP") provides that the brand manufacturer will not grant a license to any other generic manufacturer to enter the market (under authority of the generic competitor's ANDA) until a defined period of time after the first filer enters. The MFEP might provide, for example, that the brand manufacturer will not grant a license to any later filer to enter the market until 180 days after the first filer enters.

95. The brand manufacturer might also agree not to grant a license to a later filer to enter before the first filer under authority of the brand's NDA. But such a restraint is properly classified as a No-AG Payment rather than an MFEP. An MFEP restricts the brand manufacturer's ability to grant a license to a later filer to enter the market under the authority of the later filer's ANDA.

96. The purpose and effect of an MFEP, like an MFE, is to cause the first filer to delay entry into the market and to compensate it for doing so. MFEPs deter later filers from trying to enter the market before the first filer. Absent the MFEP, later filers could use their own challenges to the brand manufacturer's patents as leverage to negotiate from the brand manufacturer a license to enter the market before the first filer, thereby enjoying a substantial period with the only ANDA product on the market. Those licenses would be very valuable to the later filer where the first filer has forfeited, or might forfeit, its ANDA Exclusivity.

97. Like an MFE, an MFEP results in delayed generic entry by deterring later filers from trying to gain entry before the first filer, thereby compensating the first filer for delaying its entry.

98. MFEPs and MFEs work together to deter later filers from trying to enter before the first filer and to compensate the first filer for agreeing to delay entry. In short, the Hatch-Waxman Amendments leave open at least two pathways for later filers to enter the market before a first filer that has agreed to delay entry into the market. The later filer could win the patent litigation and trigger forfeiture of the first filer's ANDA Exclusivity when it fails to enter the market within 75 days of the court decision; and the later filer could negotiate an earlier entry date from the brand manufacturer and enter the market if the first filer has forfeited, or might forfeit, its ANDA Exclusivity.

99. The brand manufacturer and the first filer can work together, through No-AG Payments, MFEs, and MFEPs, to close *all* of the pathways to earlier generic entry that Congress left open.

VI. ASSERTIO/SANTARUS AND LUPIN MADE AN UNLAWFUL NO-AG PACT.

A. Assertio/Santarus Marketed Branded Glumetza.

100. The active ingredient in Glumetza is metformin hydrochloride. For decades, metformin has been one of the most commonly prescribed oral medications for the treatment of Type 2 diabetes. It improves glycemic control.

101. On June 3, 2005, the FDA approved Assertio's NDA for Glumetza 500 mg and 1000 mg extended-release tablets, with an indication as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes.

102. Glumetza's extended-release formulation was designed for patients experiencing issues with the efficacy of immediate-release metformin products. Doctors often found it difficult to titrate patients up to the maximum daily recommended dose of 2000 mg of metformin due to the occurrence of gastrointestinal ("GI") side effects, such as nausea. Some estimates state that up to 50% of metformin-treated patients report GI side effects, and many of those who were unable to tolerate the effects failed to achieve adequate glycemic control.

103. Glumetza's extended-release mechanism works by causing the pill, once ingested into the stomach, to swell with water. The increased size serves the dual purpose of blocking the drug's

exit from the stomach while steadily controlling the drug's release over the course of hours. This ensures the drug's release will occur in the stomach or upper GI tract, rather than the lower GI tract, thereby reducing the risk of GI side effects.

104. Glumetza was thus uniquely positioned in the market to offer patients with Type 2 diabetes an ability to reach their optimal dose of metformin with fewer GI side effects.

105. Under the NDA, Assertio listed several patents in the Orange Book for which it was the owner or licensee. For the 500 mg Glumetza product, Assertio listed the following patents:

Patent No.	**Expiration**
6,340,475 ('475 patent)	9/16/2016
6,635,280 ('280 patent)	9/16/2016
6,488,962 ('962 patent)	6/20/2020
6,723,340 ('340 patent)	10/25/2021

106. For the 1000 mg Glumetza product, Assertio listed in the Orange Book the following patents:

Patent No.	**Expiration**
6,488,962 ('962 patent)	6/20/2020
7,780,987 ('987 patent)	3/23/2025
8,323,692 ('692 patent)	3/23/2025

107. In October 2008, Santarus began promoting Glumetza under an exclusive-promotion agreement with Assertio. In August 2011, Santarus and Assertio entered into a new Commercialization Agreement pursuant to which Santarus became the NDA owner and assumed broader commercial, manufacturing, and regulatory responsibilities, including exclusive rights to manufacture and commercialize Glumetza in the United States.

108. Under the agreement, Santarus assumed sole decision-making authority on pricing, contracting, and promotion for Glumetza. Santarus also had the exclusive right to commercialize authorized-generic versions of the drug.

109. Under the Commercialization Agreement, Santarus agreed to pay Assertio a gradually increasing royalty rate (reaching a ceiling of 34.5% by 2015) on net sales of Glumetza before generic Glumetza entry. In the event of generic Glumetza entry, the parties agreed to equally share proceeds based on a gross margin split.

110. In addition, the Commercialization Agreement provided that Assertio would manage any patent-infringement lawsuits relating to patents covering Glumetza, subject to certain consent rights in favor of Santarus, including with regard to any proposed settlements. The parties also agreed to split the costs of any patent lawsuit, with Santarus responsible for 70%, and Assertio responsible for 30%.

B. Glumetza's Narrow Patents Could Not Prevent Generic Competition.

111. Glumetza's patent protection was particularly narrow. The patents did not purport to claim metformin. Nor did they purport to claim a pharmaceutical formulation (e.g., tablet, capsule, injection) of metformin alone or the method of using metformin alone to treat diabetes. The drug substance had long since been used in pharmaceutical formulations to treat Type 2 diabetes. Instead, all of the relevant patents relate to oral dosage forms that provide extended, controlled release of a drug such as metformin.

112. The patents further did not purport to broadly claim controlled-release technology. That technology was developed in the 1970's and has since been used in a variety of applications. Controlled-release technology typically involves a polymeric formulation, which is a large molecule composed of repeating structural units, using either "reservoir" or "matrix" systems.

113. In a reservoir system, a core containing the active drug is coated with an acrylic polymer composition to help achieve extended release.

114. In a matrix system, the drug is dissolved or dispersed throughout the polymer and then formulated into a pill. After the patient swallows the pill, gastric fluids cause the matrix to swell to a size large enough to maintain the dosage form in the stomach during the fed mode, *i.e.*, after a meal. This water-swollen polymeric matrix controls the rate at which the drug is released from the dosage form.

115. Glumetza's patents focus on a narrow range of formulations and methods that require a matrix controlled-release system. Assertio's patents did not even purport to invent the matrix system for metformin. Indeed, there were many prior-art options for extended-release delivery vehicles targeting the stomach, including: (i) a solid matrix formed of a substance that absorbs gastric

fluid and swells as it absorbs fluid to extend gastric retention of the delivery vehicle, such as disclosed in U.S. Patent No. 5,007,790, "Sustained-Release Oral Drug Dosage Form," issued April 16, 1991; (ii) a matrix that limits the rate at which the surrounding gastric fluid diffuses through the matrix, reaches the drug, dissolves the drug, and diffuses out again; and (iii) a matrix that slowly erodes, continuously exposing fresh drug to the surrounding fluid, such as disclosed in U.S. Patent No. 4,915,952, "Composition Comprising Drug, HPC, HPMC, and PEO," issued April 10, 1990.

116. Glumetza's patents narrowly pertained to a particular type of water-swollen polymeric matrix that is responsible for controlled drug delivery. Glumetza's patents require, among other things, particular drug-release rates, drug-to-polymer ratios, dosage forms of particular sizes and shapes and duration, the use of specific polymers in sufficient quantities to perform the required functions, and specific manufacturing processes. One or more of these claim limitations define the purported inventions.

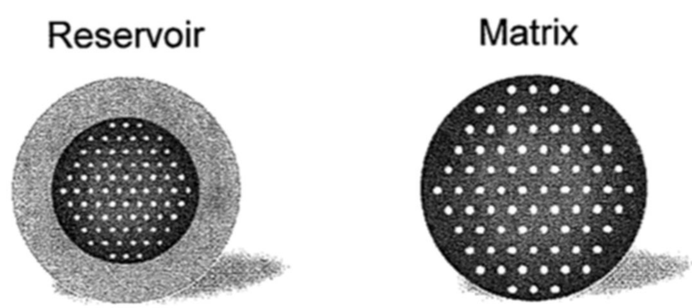
117. Assertio, as the party asserting infringement, would have the burden of proving that the generic manufacturer's product falls within every limitation of an asserted patent's claim; a generic manufacturer would prevail if its product fell outside even just one limitation of each asserted claim.

118. Generic manufacturers could avoid infringing—they could "design around"—the patents by forgoing the "matrix system" altogether. They could instead use the entirely different "reservoir system," designed to provide controlled release of the drug without, for example, "substantially retain[ing] its size and shape without deterioration until the plateau of the dissolution profile characterizing drug release from the swollen dosage form is reached or remaining substantially intact until substantially all of the drug is released." A generic version of Glumetza using such a reservoir system would necessarily fall outside all the relevant patents' claims.

119. As noted, the prior art already taught how to incorporate a reservoir system, defined as using a core containing the active drug that is coated with an acrylic polymer composition to help achieve extended release. For example, U.S. Patent No. 4,954,350, "Pharmaceutical Formulations Containing Acrivastine," issued September 4, 1990, (the "PFCA patent") discloses controlled-release pharmaceutical formulations for oral administration of acrivastine (an anti-histamine) utilizing a core

containing the drug coated with acrylic polymers. The PFCA patent specifically identifies a neutral polymer based on ethyl acrylate and methyl methacrylate, Eudragit E30D ("Eudragit"), as one of the commercially available acrylic polymers that can be used as a coating. The PFCA Patent also discloses other prior art references of delayed-release formulations containing a core of other active ingredients coated with a polyacrylate insoluble that is dispersible in water, such as Eudragit.

120. In short, a pivotal difference between the matrix and reservoir systems is the rate-controlling mechanism. In a matrix system, the mechanism controlling the rate of drug release is the polymeric matrix. In a reservoir system, by contrast, the rate-controlling mechanism is a polymeric membrane encasing the drug core.



121. Although the FDA requires generics to meet certain "sameness" requirements, having an identical controlled-release mechanism is not among them. So long as the generic manufacturer can assure the FDA that its product releases the drug at a similar rate and to a similar extent as the branded reference drug (thereby establishing bioequivalence), the FDA will not block the generic's approval on the ground that it uses a different controlled-release mechanism, such as a reservoir system.

122. Lupin's use of a reservoir system avoided each of Assertio's patents listed in the Orange Book as identified above.

123. Assertio's '475 and '280 patents are based on the same initial patent application and thus disclose the same invention. Both patents require a controlled-release dosage form in which a "drug is dispersed in a polymeric matrix that is water-swellable." As the patents explain, "the swelling of the polymeric matrix ... achieves two objectives—(i) the tablet swells to a size large

enough to cause it to be retained in the stomach during the fed mode, and (ii) it ... provide[s] multi-hour, controlled delivery of the drug into the stomach." In this way, "[t]he rate limiting factor in the release of drug is therefore controlled diffusion of the drug from the matrix." Accordingly, the basic and purportedly novel properties of the '475 and '280 patents are the *polymeric matrix*'s ability to control the rate of drug release from the dosage form by swelling to promote retention in the stomach and having an erosion rate that is substantially slower than its swelling rate.

124. A reservoir system can achieve the desired controlled release without relying on a polymeric matrix having the properties required by the '475 and '280 patents. A reservoir system wraps the drug core with a separate polymer coat that contains distinct chemical properties and represents an insoluble, physical barrier. The rate-limiting factor in the release of the drug is controlled by the diffusion not from the matrix, as would be required under the'475 and '280 patents, but from the polymer coat.

125. Due to their narrowness, neither the '475 patent nor the '280 patent could prevent a generic Glumetza product from launching before those patents expired in September 2016. Having been listed in the Orange Book for only Glumetza's 500 mg strength, they clearly could not block approval of a generic Glumetza 1000 mg ANDA. Regardless, the patents' narrow scope could not prevent a generic manufacturer from receiving FDA approval and launching generic versions of Glumetza 500 and 1000 mg, especially ones using a reservoir system.

126. Use of a prior-art reservoir system also allowed a generic manufacturer to design around the remaining, later-expiring Glumetza patents.

127. The '962 patent merely purports to offer an improvement over the '475 and '280 patents and covers "tablet shapes to enhance gastric retention of swellable controlled-release oral dosage forms." In terms of avoiding infringement, the "consisting essentially of" claims of the '962 patent can be avoided either by a dosage form having a shape that differs from that claimed or by using a delivery vehicle that materially differs from that of a solid monolithic matrix. A generic manufacturer would avoid infringing the '962 patent simply by virtue of using a non-swellable polymer coat, rather than a matrix, which materially affects the dosage form to control the drug's release.

128. Also very narrow, the ‘340 patent purportedly covers optimal material to be used in the matrix in order for it to control the drug’s release. So, again, a generic manufacturer would easily avoid infringing the ‘340 patent by using the host of other available materials to carry the drug rather than the specific claimed matrix of poly(ethylene oxide) and hydroxypropyl methylcellulose, to control the drug’s release.

129. Both the ‘987 and ‘692 patents disclose a dosage form requiring a controlled-release coating that must be prepared by “curing the coated oral dosage form at a temperature of at least 55° C” and must consist of a neutral ester copolymer, a polyethylene glycol, one or more hydrophilic agents, and a pharmaceutically acceptable excipient. A generic manufacturer would easily design around those patents’ claims by applying a different prior art coating to control the drug’s release.

130. The ‘987 and ‘692 patents, having been listed for only the 1000 mg Glumetza product, clearly could not block a generic Glumetza 500 mg ANDA. Regardless, the patents’ narrow scope could not prevent a generic manufacturer from receiving FDA approval and marketing generic versions of Glumetza 500 and 1000 mg.

C. Assertio Sued Lupin, Whose Potential Competition Threatened Growing Glumetza Business.

131. The active ingredient in Glumetza, *i.e.*, metformin, was not patent protected, and other acceptable delivery vehicles existed in the prior art. Lupin therefore recognized the opportunity to develop and market a competing generic Glumetza product substantially before Glumetza’s patents expired.

132. On or about July 27, 2009, Lupin filed ANDA 91664 seeking FDA approval to manufacture and sell a generic version of Glumetza 500 mg and 1000 mg. Lupin’s ANDA contained a paragraph IV certification to all applicable Glumetza patents. At the time, Assertio had listed in the Orange Book only the ‘475, ‘280, ‘962, and ‘340 patents for Glumetza.

133. On or about November 6, 2009, Lupin notified Assertio that Lupin had filed ANDA 91664, detailing why the relevant patents were both invalid and not infringed by Lupin’s ANDA product.

134. On November 25, 2009, Assertio sued Lupin in the U.S. District Court for the Northern District of California, claiming infringement of the ‘475, ‘280, ‘962, and ‘340 patents. Assertio’s timely lawsuit triggered the Hatch-Waxman Act’s automatic 30-month stay against Lupin’s entry into the market, measured from the date Assertio received Lupin’s November 6, 2009 paragraph IV notice letter.

135. Assertio filed the patent infringement lawsuit against Lupin without regard to the lawsuit’s merits. In fact, Assertio knew that there was an overwhelming likelihood that it would lose the patent litigation. Assertio’s true purpose in bringing the lawsuit was to ensure it received the automatic 30-month hiatus from generic competition. Simply by filing the case, Assertio effectively excluded Lupin from obtaining FDA approval and coming to market until May 6, 2012.

136. On January 29, 2010, Lupin filed its answer to Assertio’s complaint, asserting that the manufacture, use, offer for sale, sale, or importation of its ANDA product would not infringe any valid and enforceable claim of the relevant patents.

137. As the litigation proceeded, Assertio dropped its claim of infringement relating to the ‘340 patent.

138. On August 26, 2011, Lupin provided supplemental interrogatory responses disclosing that its ANDA product does not and cannot infringe Assertio’s patents because it uses a reservoir system rather than a polymeric matrix system to extend the drug’s release.

139. Relying on key differences between its reservoir-system product and the matrix-system products claimed under the Glumetza patents, Lupin established that its product does not meet the patents’ requirements that: (i) the product remain “substantially intact” until all of the drug is released; (ii) the product’s drug core “substantially retain its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles” until “at least about 80% of the drug has been released after eight hours of immersion in gastric fluid”; and (iii) “the drug is released at a rate controlled by the rate of diffusion” out of the polymeric matrix.

140. Lupin further explained that its reservoir delivery system used a coating that included Eudragit to control the drug’s release, rather than being controlled by the polymeric matrix core as

required by the Glumetza patents. As stated above, controlled-release delivery vehicles based on a coating containing acrylic polymers, such as Eudragit, were well known in the prior art.

141. On January 27, 2012, the FDA tentatively approved Lupin's ANDA, meaning that Lupin's ANDA product could receive final approval for marketing as an AB-rated generic as early as the expiration of the 30-month stay in May 2012. After final approval, Lupin would be eligible to launch its generic Glumetza at risk—before a final, non-appealable judgment in the patent case. The tentative approval thus signaled to Assertio and Santarus a significant risk that Lupin was just months away from launching a non-infringing AB-rated generic Glumetza. Moreover, even if Lupin waited until its victory in the trial, Lupin would likely enter the market in late 2012 or early 2013 because the patent case was scheduled for trial in October 2012.

142. Lupin's marketing generic Glumetza would have devastated Assertio/Santarus's bottom line. As of January 2012, Glumetza represented more than 50% of Santarus's sales.

143. Lupin posed a particularly significant threat of launching at-risk. In September 2011, Lupin had launched at-risk a generic version of Fortamet. Like Glumetza, Fortamet consisted of 500 mg and 1000 mg extended-release tablets of metformin hydrochloride. And Lupin had launched generic Fortamet shortly after expiration of that 30-month stay—exactly the same juncture that Lupin was then approaching in the Glumetza litigation.

144. Santarus and Assertio also knew that, if the litigation proceeded, the overwhelming likelihood was that the Lupin product would be found not to infringe the Glumetza patents. As alleged above, Lupin's generic used a reservoir system, which is not covered by the relevant patents. Lupin thus had an extraordinarily small likelihood that any at-risk launch would later subject it to liability for patent damages.

145. In short, Santarus and Assertio believed, correctly, that Lupin intended to begin marketing generic Glumetza in May 2012 unless the parties settled the patent litigation.

D. Assertio/Santarus Paid Off Lupin to End the Risk of Competition.

146. To avoid the substantial probability that Lupin would launch a non-infringing generic Glumetza either at risk or after prevailing in court, Assertio and Santarus decided to extend the

period of Glumetza's supracompetitive profits by paying Lupin to withdraw its patent challenges and delay introducing generic Glumetza.

147. On February 22, 2012—just after Lupin's January 2012 tentative approval and shortly before the 30-month stay would expire in May 2012—Assertio/Santarus and Lupin entered into an agreement whereby Lupin agreed to end its challenge to the Glumetza patents and substantially delay entering the market, in exchange for a No-AG pact.

148. Under the agreement, Lupin agreed to refrain from entering the market with a generic Glumetza until February 1, 2016 (subject to the MFE and MFEP clauses discussed below). In exchange for Lupin's agreeing to delay its entry for nearly four years, Assertio/Santarus agreed not to market an authorized generic Glumetza 500 mg and 1000 mg product, and not to license any other manufacturer to market such a product under Assertio's NDA, for *at least* 180 days after Lupin's entry into the market (the "No-AG Payment").

149. Plaintiff has reason to believe that the term of the No-AG clause secretly extended an entire year following Lupin's launch, not just 180 days. Valeant in fact refrained from entering the market with its authorized generic version of Glumetza until February 2017—a year after Lupin's entry.

150. The purpose and effect of the No-AG Payment was to induce Lupin to abandon its patent challenge and agree not to compete with a generic version of Glumetza until February 2016. Assertio/Santarus would not have agreed to the No-AG Payment without securing, in exchange, Lupin's agreement not to market a generic version of Glumetza until February 2016. Likewise, Lupin would not have agreed to a delayed February 2016 entry without securing, in exchange, Assertio/Santarus's commitment to the No-AG Payment.

151. Absent the No-AG Payment, Santarus had the incentive and ability to market an authorized generic version of Glumetza immediately upon (if not before) Lupin's entry. For example, Santarus launched an authorized generic simultaneously with the first filer's launch of generic Zegerid. A rational profit maximizing entity in Santarus's position would not forgo an opportunity to gain additional sales by marketing an authorized generic. Indeed, Santarus ensured

that its commercialization agreement with Assertio gave Santarus the right to launch a Glumetza authorized generic.

152. By giving up the unqualified right to earn profits from marketing its own authorized generic, Santarus enabled Lupin to make approximately twice the unit sales, at a much higher price, all at the expense of Plaintiff and Class members. The No-AG Payment thus served as substantial compensation for Lupin's agreement to delay its entry, and Lupin could not have obtained this payment or its equivalent even if Lupin had won the patent litigation against Assertio.

153. The No-AG Payment's value to Lupin is readily calculable using the known economics of the pharmaceutical industry. Assuming, conservatively, that the term of the No-AG clause extended only six months, and not a year as suspected, the valuation from Lupin's perspective is a matter of estimating the additional sales it expected to make during its first six months of marketing in 2016 compared to the sales it expected to make in the first six months of entry in 2012 when, without the benefit of the No-AG Payment, it would have faced competition from Santarus's authorized generic.

154. For 2012, annual sales of Glumetza were approximately $150 million. Six months (180 days) of brand Glumetza sales would generate revenue to Assertio/Santarus of $75 million (6/12 * $150 million).

155. Lupin expected generics to take 80% of Glumetza unit sales during those six months. Thus, Lupin expected generics to capture approximately $60 million worth of brand units during those six months ($75 million * 0.8).

156. In the absence of a No-AG Payment, Lupin expected two generics (its own, and Santarus's authorized generic) to be in the market during those 180 days. Studies by the FDA and others show that, with two generics in the market, the average generic price is driven down to a 48% discount off the brand price. Lupin expected that the two generics would sell the $60 million worth of brand units during those six months for a total of $31.2 million ($60 million * .52).

157. Lupin expected, however, that it would not get all of those revenues. Instead, the unit sales of the generic during the six months would be split (roughly evenly) between Lupin and the Santarus authorized generic. In fact, the authorized generic often captures more than half of the unit

sales due to a "first-mover" advantage and other marketing advantages. Thus, without a No-AG Payment, Lupin expected that its revenues during the six months would be at most $15.6 million ($31.2 million * .5).

158. *With the anticompetitive No-AG pact*, Lupin knew that it would fare far better financially. First, Lupin would make 100% (not 50%) of the generic sales in the first six months.

159. Second, Lupin would make those sales at a far higher price. Lupin knew that the absence of a competing generic would enable it to sell its generic Glumetza at only a 10% discount off the price of the brand, rather than a 48% discount.

160. Third, Lupin expected that the brand sales revenue, driven by both increased unit sales and increased prices, would be far higher in 2016 than it would be in 2012. Santarus had just recently assumed full responsibility for commercializing Glumetza. Its sales were quickly rising, having doubled in the first quarter of 2012 compared to the first quarter of 2011. Santarus had just hired 30% more sales representatives and rolled out a new promotional program, prompting analysts to predict very significant sales growth. Consequently, Lupin expected annual brand sales as of 2016 to be at least $200 million.

161. Thus, with a No-AG clause in place, Lupin expected the value of its generic Glumetza sales during the six-month period in 2016 to be at least $72 million ($200 [annual brand sales] *.5 [six months] * .8 [percent of sales taken by generic] * .9 [10% price discount]).

162. The No-AG Payment's value to Lupin was, at a minimum, the difference between the value of six months of marketing in 2012 with an authorized generic on the market, and six months of marketing in 2016 without an authorized generic on the market. That difference is $56.4 million ($72 – $15.6). The No-AG Payment's value to Lupin was far more than it could have made *even if it had won the patent litigation*.

163. In fact, Lupin knew that the No-AG Payment's value to it far exceeded $56.4 million, even setting aside the potential that the No-AG clause's term was for a year rather than a half-year. Lupin knew and intended that its agreeing to delay entry until 2016 would encourage Assertio/Santarus to exploit the market power that Lupin's agreement had secured for them. As set forth further in detail below (see Section VIIIA), Assertio/Santarus got that bought-and-paid-for

monopoly into the hands of another brand manufacturer that was able to fully exploit it. That manufacturer—Valeant—used the generic-free time period to raise the price of branded Glumetza by nearly 800%, causing the dollar sales to rise to more than $1.2 billion annually by 2016.

164. Thus, the No-AG Payment resulted in Lupin's making sales in the six-month period in 2016 of some $295 million. This is $280 million more than Lupin would have made by marketing the product for six months in 2012 with an authorized generic on the market. And this assumes that the No-AG clause's term was only six months rather than a year.

165. The No-AG Payment resulted in Assertio/Santarus's forgoing between $15.6 million and $31.2 million in sales of an authorized generic in 2012 (depending on whether the No-AG clause's term was six months or a year). But the No-AG Payment caused Lupin to delay entry into the market by nearly four years. That delay was worth more than $2.8 billion to Assertio/Santarus and their successors. And that's how much Glumetza purchasers have been overcharged.

166. Assertio/Santarus's No-AG Payment to Lupin impaired competition in at least three ways. It: (a) allocated 100% of the Glumetza market to Assertio/Santarus for the period before generic competition; (b) allocated 100% of the generic segment of the market to Lupin for at least 180 days; and (c) substantially delayed entry by *all* generic manufacturers.

167. Had Assertio/Santarus not paid Lupin to drop its patent challenge and delay entry into the market, Lupin would have marketed its less expensive generic Glumetza: (a) "at-risk" (*i.e.*, while the patent litigation was pending) upon the expiration of the 30-month stay; (b) upon winning the patent litigation; or (c) earlier than February 1, 2016, on a date to be determined by a jury, pursuant to a lawful settlement agreement without a large unjustified payment from Assertio/Santarus to Lupin. Absent the No-AG Payment, immediately upon Lupin's entry into the market (or before), Assertio/Santarus, as a rational economic actor seeking to recoup lost branded sales, would have sold authorized generic Glumetza in competition with Lupin, driving prices down even further.

168. Defendants have no procompetitive explanation or justification for the No-AG Payment. The large, unjustified payment had no rational connection to, and far exceeded, any approximation of the costs of continuing the patent litigation. Typical litigation costs for patent cases

of this nature rarely exceed $5.5 million. Assertio/Santarus's future expected litigation costs at the time it unlawfully paid Lupin—after two years of patent litigation—were much less than that.

169. The No-AG Payment was anticompetitive and unlawful regardless of whether it constitutes a reverse payment.

VII. ASSERTIO/SANTARUS AND LUPIN NEUTRALIZED COMPETITION FROM LATER FILERS.

A. Later Filers Were Poised to Upend the Anticompetitive No-AG Pact.

170. The No-AG Payment significantly delayed competition between Assertio/Santarus and deprived Glumetza purchasers of dramatically lower prices. But other potential sources of competition remained: other generic manufacturers. So Assertio/Santarus and Lupin included other anticompetitive provisions in their settlement to neutralize those potential threats.

171. As the first filer, Lupin was eligible to receive the 180-day ANDA Exclusivity. As described in detail above (see Section VF), however, Congress left open pathways for later-filer generic manufacturers to try to come to market before the entry date agreed between the first filer and the patent holder, despite the 180-day ANDA Exclusivity. Those later filers can enter the market with their ANDA-approved products even where the FDA has awarded 180-day ANDA Exclusivity to the first filer. (The No-AG Payment precluded Assertio/Santarus from allowing a later filer to enter before Lupin pursuant to a license under Assertio's NDA.)

172. As applicable here, a later filer could get a final court decision that its generic Glumetza product did not infringe any of Assertio's valid patents. In that event, Lupin would forfeit its ANDA Exclusivity if it failed to enter the market within 75 days of the court decision. 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb). Having agreed to delay entry until February 1, 2016, Lupin *would* fail to enter within 75 days, and therefore *would* forfeit, if a later filer got the final court decision before November 18, 2015. That forfeiture would allow the later filer to enter before Lupin. After Lupin forfeited its ANDA Exclusivity, even more later filers could enter before Lupin. They could enter before Lupin by winning their patent litigations or using the leverage of their patent challenges to get a license from Assertio/Santarus.

173. Two circumstances created an overwhelming likelihood that Congress's incentives for a later filer would work, resulting in a final court decision that deprived Lupin of ANDA Exclusivity. First, as described in detail above (see Section VIB), Assertio's patents on Glumetza were very narrow and could easily be designed around. Lupin could and did design around them simply by using a reservoir system rather than a matrix system. Assertio/Santarus and Lupin knew that other generic manufacturers could do the same thing.

174. Second, Lupin agreed to a very long delay in generic entry—nearly four years. As described in detail below (see Section VIIA), in February 2012 when Assertio/Santarus and Lupin agreed to their No-AG Payment, later filer Sun Pharmaceutical was well into its patent litigation with Assertio/Santarus. That litigation could reasonably be expected to be completed, through a final court decision, by no later than February 2015. Sun Pharmaceutical could therefore expect a very substantial reward, in the form of a year or more of exclusive or semi-exclusive sales in the generic sector, for getting onto the market before Lupin.

175. Assertio/Santarus and Lupin avoided that probability by including an MFE and an MFEP in their agreement. The MFE provided that, if any other generic manufacturer succeeded in entering the market with generic Glumetza before Lupin's scheduled February 1, 2016 date, Lupin's entry would be moved up accordingly. The MFEP provided that Assertio/Santarus would not grant a license to any other manufacturer to enter the market with generic Glumetza until a date that was at least 180 days after Lupin entered.

176. Without the MFE and MFEP, Lupin faced a high likelihood that it would be stuck on the sidelines while later filers entered the market a year or more in advance and reaped the corresponding gains of being the first ANDA entrants.

177. Congress intentionally left open those pathways for later filers to enter first and enjoy periods of exclusivity or semi-exclusivity. Those pathways created incentives for later filers to enter the market before a delayed entry date to which a first filer agreed. As described in detail above (see Section VF), the purpose and effect of MFEs and MFEPs is to undermine those incentives. The MFE and MFEP agreed between Assertio/Santarus and Lupin ensured that later filers could not in fact

benefit from the two pathways (litigation victory or better license) that Congress intentionally left open for later filers to improve on the entry date to which Lupin had agreed.

178. In short, Assertio/Santarus and Lupin's purpose in agreeing to the MFE and MFEP was to (1) deter later filers from trying to enter the market before Lupin's delayed February 2016 entry date; and (2) by eliminating the threat that later filers would use the statutory incentives to eliminate Lupin's ANDA Exclusivity, compensate Lupin for agreeing to that four-year delay. The MFE and MFEP deterred later filers from trying to enter the market before Lupin, in return for which Lupin agreed to later entry.

B. The MFE and MFEP Delayed Later Filers' Entry.

1. The MFE and MFEP Delayed Sun's Entry.

179. Assertio/Santarus and Lupin's anticompetitive scheme worked. The MFE and MFEP succeeded in preventing any other generic manufacturer from entering the market before Lupin's delayed entry date.

180. Sun Pharmaceuticals (Pharma Global FZE, Sun Pharmaceutical Industries Ltd., and Sun Pharmaceutical Industries Inc.—collectively, "Sun") was the second manufacturer (Lupin being the first) that filed an ANDA seeking to market generic versions of Glumetza 500 mg and 1000 mg tablets before the expiration of the Orange Book-listed patents.

181. On or about May 6, 2011, Sun notified Assertio that Sun had filed ANDA 202917, detailing why its generic Glumetza did not infringe a valid claim of the relevant Orange Book patents.

182. On June 20, 2011, Assertio filed a lawsuit in the U.S. District Court for the District of New Jersey against Sun asserting infringement of the '962, '340, '280, '475, and '987 patents listed in the Orange Book. Valeant International Bermuda ("VIB") joined in the lawsuit as a co-plaintiff because it owned the '987 patent and exclusively licensed it to Assertio. Assertio and VIB sued Sun within 45 days of receiving the paragraph IV certification, so the automatic 30-month stay prohibiting Sun's entry into the market started to run on or about May 6, 2011 and would expire on or about November 6, 2013.

183. Assertio also sued Sun for infringement of U.S. Patent No. 7,736,667 ("the '667 patent"), which is not listed in the Orange Book. The '667 patent discloses a dual-matrix, controlled-release oral dosage form. The first matrix—the "core"—is comprised of a water-swellable polymeric material "in which drug is dispersed." The second matrix—the "shell"—forms a "casing that surrounds and fully encases the core." This shell is comprised of a water-swellable polymeric material "that swells upon imbibition of water (and hence gastric fluid) to a size large enough to promote retention in the stomach during the fed mode[.]" A drug employing a reservoir system does not, by definition, use a dual-matrix system with a core and shell that each swell upon imbibition of water. Thus, the '667 patent, like the other Glumetza patents, was not likely to pose a bar to a generic that uses a reservoir system.

184. Like Lupin before it, Sun denied that the relevant patents covered its ANDA product, asserting that its proposed generic tablet controlled the release of metformin using a reservoir system in which a drug core is covered by a polymeric membrane, rather than a matrix system claimed under the patents.

185. On January 25, 2013, Assertio/ Santarus and VIB entered into an agreement that terminated Sun's challenge to the Glumetza patents. During the negotiations leading to that agreement, Sun knew that Assertio/Santarus had agreed to an MFE and MFEP with Lupin, which significantly diminished Sun's incentive to continue its challenge. Consequently, Sun agreed that it would not begin selling a generic version of Glumetza until August 1, 2016—180 days after Lupin's delayed entry date.

186. It is unknown to Plaintiff at the present time whether Assertio/Santarus made any payment to Sun to help ensure that it would not enter the market before August 2016.

2. The MFE and MFEP Delayed Watson's Entry.

187. Watson Pharmaceuticals (Watson Laboratories, Inc.–Florida, Watson Pharmaceuticals, Inc., and Watson Pharma, Inc.—collectively "Watson") was the third generic that filed an ANDA for generic Glumetza before expiration of the Orange Book patents. Initially, Watson filed an ANDA for only a 1000 mg product.

188. On or about March 7, 2012, Watson notified Assertio and VIB that Watson had filed ANDA 203755, detailing why its generic Glumetza 1000 mg would not infringe a valid claim of the relevant Orange Book patents.

189. On April 18, 2012, Assertio and VIB filed a lawsuit in the U.S. District Court for the District of Delaware against for infringement of the patents listed in the Orange Book for Glumetza 1000 mg at the time the lawsuit was filed (the ‘962 and ‘987 patents). Assertio and VIB sued Watson within 45 days of receiving the paragraph IV certification, and the automatic 30-month stay prohibiting Watson’s entry into the market would expire on or about September 7, 2014.

190. In February 2013, Assertio and VIB amended their complaint to add infringement of a newly listed Orange Book patent (the ‘692 patent), as well as two non-Orange Book listed patents (the ‘667 patent and U.S. Patent No. 8,329,215 (“the ‘215 patent”)).

191. The ‘215 patent, like the ‘667 patent, discloses a dual-matrix system where a dosage form employs a core and shell that each swell upon imbibition of water. As explained above, a product using a reservoir system does not have such properties and so falls outside the scope of the ‘215 patent’s claims.

192. On February 28, 2013, Assertio filed a new complaint in the U.S. District Court for the District of Delaware against Watson for infringement of the ‘962, ‘340, ‘280, ‘475 patents. Assertio filed the lawsuit in response to Watson’s providing Assertio a paragraph IV notice letter, dated January 18, 2013, stating that Watson had amended its ANDA 203755 with the intent to market a generic version of Glumetza 500 mg tablets, in addition to the previously noticed 1000 mg tablets, before the relevant Orange Book-listed patents expired. The 30-month stay automatically precluding Watson’s generic Glumetza 500 mg product would not expire until on or about July 18, 2015.

193. On November 8, 2013, Assertio/Santarus and VIB entered into an agreement that terminated Watson’s challenge to the Glumetza patents. During the negotiations leading to that agreement, Watson knew that Assertio/Santarus had agreed to an MFE and MFEP with Lupin, which significantly diminished Watson’s incentive to continue its challenge. Consequently, Watson agreed that it would not begin selling a generic version of Glumetza until August 1, 2016—180 days after Lupin’s delayed entry date.

194. It is unknown to Plaintiff at the present time whether Assertio/Santarus made any payment to Watson to help ensure that it would not enter the market before August 2016.

195. Absent the No-AG Payment, MFE, and MFEP to which Assertio/Santarus and Lupin agreed, Sun and Watson would have entered the market much sooner than they did, on dates to be determined by the jury. The delay in generic entry protected more than $2.8 billion in branded Glumetza sales, all at the expense of Plaintiff and other Class members.

VIII. DEFENDANTS FULLY EXPLOITED THE MONOPOLY THEY CREATED.

A. Defendants Sold the Glumetza Monopoly to Valeant—A Ruthless Exploiter of Drug-Product Monopolies.

196. The Glumetza monopoly that Assertio/Santarus and Lupin created and maintained was a very valuable asset. They wasted no time in getting it into the hands of a commercial entity that mercilessly and ruthlessly exploited it, with devastating consequences for Glumetza purchasers.

197. As of February 2012, Assertio/Santarus was selling branded Glumetza at more than five times the price that a fully competitive generic sector would have delivered. Glumetza purchasers could get relief from that high price through three potential means: entry by Lupin; entry by a Santarus authorized generic; or entry by later filers. The No-AG Payment between Assertio/Santarus and Lupin extended the Glumetza monopoly by four years rather than ending it and compounded the injury by ensuring the absence of an authorized generic (whether sold by Santarus or a licensee) once Lupin belatedly entered the market. Assertio/Santarus and Lupin also agreed to the MFE and MFEP to ensure that no later filers would upend their anticompetitive scheme by entering the market with an ANDA generic before Lupin's delayed entry date. The No-AG Payment, MFE, and MFEP closed off every available avenue of generic competition. Rather than ending the Glumetza monopoly, those clauses ensured that it would extend for at least another four years.

198. That guaranteed four-year monopoly was enormously valuable, and Assertio/Santarus immediately cashed in on it by selling it to those who could more effectively exploit it. Through the anticompetitive conduct described above, Assertio/Santarus had pushed Lupin's entry out to

February 2016 and Sun's and Watson's out to August 2016. The last piece of that anticompetitive trifecta was the agreement that Assertio/Santarus and Watson announced on November 8, 2013.

199. On November 7, 2013, Defendant Salix announced that it had reached an agreement to acquire Santarus. Salix withheld final agreement to that acquisition until it was assured that Assertio/Santarus had reached a deal with Watson to delay marketing its generic Glumetza until August 2016. Salix's CEO reported to stock analysts that Salix was "comfortable" with the acquisition because Glumetza would not be "lost to generics" until 2016.

200. When Salix was negotiating for the acquisition, Glumetza accounted for just under half of Santarus's annual sales. Under the acquisition agreement, Salix agreed to pay $2.6 billion for Santarus. That purchase price represented a 37% premium to Santarus's share price before the acquisition was announced.

201. Then Salix too cashed in on the Glumetza-monopoly sweepstakes. Just 13 months after acquiring Glumetza, in February 2015 Salix announced that it was being acquired by Valeant.

202. When Valeant acquired Salix in April 2015, Glumetza accounted for more than 25% of Salix's sales. Valeant paid $14.5 billion for the Glumetza monopoly and the other Salix assets.

203. The Glumetza monopoly was the perfect asset for Valeant to acquire. Valeant did not believe in developing new drugs for the betterment of people. It believed in buying existing drug-product monopolies and exploiting them to the fullest extent. During the relevant time here, Valeant's annual Research and Development budget was less than 3% of its revenues, about a fifth of the pharmaceutical industry average. The motto of Valeant's CEO was "Don't bet on science—bet on management." And he called investing in pharmaceutical research "a losing proposition."

204. Valeant's board of directors implemented its "forget science, exploit existing monopolies" strategy by operating the company like a hedge fund and paying its executives as if they were hedge-fund managers. Valeant paid relatively little cash compensation to top executives but granted them huge stock options that vested only if the company reached aggressive revenue goals.

205. Valeant reached those goals by acquiring companies like Salix that had existing drug-product monopolies. Valeant would then slash the workforce, especially the scientists, and take enormous price increases on the already existing monopolized drugs. As Forbes magazine later

characterized it, Valeant's strategy "emphasized boosting drug prices, gutting research and development budgets, [and] firing employees." Vardi & Gara, *supra*. "[S]cientists were seen as unnecessary costs to be cut," while Valeant's "drug-price increases became legendary." *Id.* Some pharmaceutical manufacturers may refrain from fully exploiting drug monopolies, based on their longer-term outlooks or concerns about public scrutiny. Valeant had no such qualms.

206. A former Valeant executive later admitted that its culture was "We're the bad boys, we're successful, we can do whatever we want." McLean, *supra*. The CEO admitted publicly that "[a]ll I care about is our shareholders" and that, "from [an investor's] standpoint [raising prices] is not a bad thing." *Id.* Unsurprisingly, industry observers concluded that "Valeant was the pure expression of the view that companies are there to make money for shareholders, every other consideration be damned." *Id.*

207. Glumetza purchasers were among the "every other consideration" that Valeant scorned. Immediately after acquiring the Glumetza monopoly, Valeant applied its corporate strategy of fully exploiting existing monopolies. Valeant bought the Glumetza monopoly from Salix in April 2015. By the end of that July, Valeant had raised the price of a 30-day supply by more than 750%, from $350 to more than $3,000. As a result, Valeant's revenues from Glumetza in the two quarters after the price increase skyrocketed from $145 million to more than $818 million.

208. Glumetza's massive price increase was made possible only by the unlawful agreements that delayed Lupin's generic entry to 2016. Valeant's price hike worked solely because a generic had not already entered the market and taken the unit sales at dramatically lower prices. Absent the No-AG Payment, Lupin would have begun marketing generic Glumetza long before Valeant's acquisition of Salix, as early as May 2012. Lupin's earlier entry thus would have deprived Valeant and anyone else of the opportunity to exploit the Glumetza monopoly.

B. Defendants Exploited the Glumetza Monopoly Through Four Years of Delayed Generic Entry, Then Another Full Year of No Competition from an Authorized Generic.

209. Valeant's exploitation of the Glumetza monopoly and other drug-product monopolies drew the attention of the U.S. Congress, which held a number of hearings into Valeant's strategy of forsaking science in favor of price increases on existing drug-product monopolies. The hearings established that Valeant set drug prices to reach pre-determined revenue goals, and "sought to exploit [its] temporary monopol[ies] by increasing prices dramatically to extremely high levels very quickly." House Comm. On Oversight and Government Reform Memorandum, *Documents Obtained by Committee from Valeant Pharmaceuticals* (Feb. 2, 2016), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on%20Valeant%20Documents0.pdf.

210. In a February 4, 2016 hearing, Representative Cummings specifically highlighted Valeant's exploitation of the Glumetza monopoly, noting that Valeant raised its price "by a whopping 800 percent over a mere six-week period." *Developments in the Prescription Drug Market: Oversight Hearing Before the House Comm. On Oversight and Government Reform*, 114 Cong., at 3, 119 (Feb. 4, 2016), *available at* https://www.govinfo.gov/content/pkg/CHRG-114hhrg25500/pdf/CHRG-114hhrg25500.pdf. He noted that Valeant's "basic strategy has been to buy drugs that are already on the market and then raise the prices astronomically [for a] temporary period of time before other competitors enter the market." *Id.*

211. In order to placate Congress, Valeant's CEO testified to the U.S. Senate on April 27, 2016 that "it was a mistake to pursue, and in hindsight I regret pursuing, transactions where a central premise was a planned increase in the prices of the medicines." Statement of J. Michael Pearson before the Senate Special Committee on Aging (Apr. 27, 2016), https://www.aging.senate.gov/imo/media/doc/SCA_Pearson_4_27_16.PDF. And he gave them the false comfort that, going forward, "[w]e expect our pricing actions to track industry norms." *Id.*

212. Yet, at that very moment, Valeant was continuing to adhere to the unlawful agreements that extended the Glumetza monopoly. Two months earlier—in February 2016—Defendant Lupin had finally entered the market with generic Glumetza, having unlawfully agreed to stay out of the market from May 2012 until February 2016.

213. By then, Valeant's ruthless exploitation of the Glumetza monopoly had raised the price of the branded product astronomically. And when Lupin entered the market, *Valeant adhered to the unlawful agreement by refraining from marketing an authorized generic*.

214. The direct result of that unlawful adherence was that Lupin, as the only generic available, was able to price its generic at a substantially smaller discount off the brand price than it otherwise would have—but could take advantage of the gigantic price increases for Glumetza that the Defendants engineered. Lupin's agreement to delay entry by four years had allowed Valeant to raise the brand price by nearly 800%. Now Valeant was adhering to the unlawful agreement by not marketing an authorized generic, which would have driven the generic price down to a 48% discount off the brand. *While Valeant was mollifying Congress with false assurances that Valeant had reformed its corporate ways*, it was both keeping its brand price at the monopoly-enabled level and depriving purchasers of the generic competition that would have cut then-current prices in half.

215. As a result, throughout 2016 purchasers of Glumetza were paying more than $3,000 per month for the brand product and *more than $2,200 per month for Lupin's generic.* Compare those prices to what would have happened if the Defendants had not entered into their unlawful agreements: Lupin would have entered the market in 2012, Assertio/Santarus would have immediately entered the market with an authorized generic, and later both Sun and Watson would have entered with their generics.

216. In 2012, the price of a 30-day supply of 1000 mg branded Glumetza was about $250. By the beginning of 2015—long before Valeant got its hands on the product and jacked up prices by more than 750%—the generics would have taken almost all of the unit sales and would have competed the price down to, at most, $55.

217. As a result of the delay in generic entry and the Defendants' full exploitation of the monopoly that the delay created, only the branded product was available in 2015. The result was that the 30-pill price after Valeant's increase was more than $3,000 rather than, at most, $55. Lupin belatedly entered the market in 2016. But the combined effect of the astronomical brand price and Valeant's agreement not to market an authorized generic was that Lupin's price for a 30-day supply *of the generic product* was more than $2,200 rather than, at most, $55.

218. Altogether, Defendants' unlawful extension of the Glumetza monopoly has already caused direct purchasers to overpay by more than $2.8 billion. And it continues to cause substantial overcharges today (and will continue to do so for the foreseeable future to) at the rate of more than $175 million every year.

219. On May 15, 2017, Teva Pharmaceutical Industries Ltd. (which had acquired Watson) began marketing its generic Glumetza 500 mg and 1000 mg. On July 25, 2018, Sun began marketing its generic Glumetza 500 mg and 1000 mg. Watson and Sun had received licenses from Assertio/Santarus to enter the market in August 2016. The reasons for their delays after August 2016 are currently unknown to Plaintiff.

220. Defendants' anticompetitive No-AG Payment, MFE, and MFEP caused Watson and Sun to agree to delay entry until August 2016, with the result that they had put development of their generic Glumetza on hold. If Defendants had not caused Watson and Sun to agree to delay entry until August 2016, they would have resolved any technical or other delay-inducing issues much sooner (or never would have encountered them to begin with), and would have entered the market before July 2015, on a date to be determined by the jury.

IX. MARKET EFFECTS

221. By impeding competition from generic Glumetza, Defendants' anticompetitive conduct caused Plaintiff and Class members to pay more than they would have paid for branded and generic Glumetza. Earlier entry of Lupin's generic Glumetza would have given purchasers the choice between branded Glumetza and AB-rated generic substitutes of Glumetza, which are priced substantially below the brand. Many purchasers would have bought the lower-priced generic drugs rather than the higher-priced branded Glumetza. Every state's pharmacy substitution laws require or encourage pharmacies to substitute AB-rated generics for branded prescription pharmaceuticals whenever possible. Absent the Defendants' anticompetitive conduct, Plaintiff and other Class members would have saved billions of dollars by paying less for branded Glumetza and purchasing generic Glumetza earlier. Defendants' anticompetitive conduct caused Plaintiff and other Class members to incur overcharges on their purchases of both branded and generic Glumetza.

222. Absent the Defendants' anticompetitive conduct, immediately upon Lupin's entry into the market, Assertio/Santarus, as a rational economic actor seeking to recoup lost branded sales, would have sold authorized generic Glumetza in competition with Lupin. As described in detail above (see Section VID), Santarus had a history of marketing authorized generics. And Santarus specifically negotiated with Assertio for the right to market an authorized generic version of Glumetza.

223. The economic rationality of marketing an authorized generic (absent an unlawful No-AG pact) is confirmed by Valeant's conduct. Valeant, through its subsidiary Oceanside, frequently markets authorized generics when its branded drugs first experience generic competition. It did so with respect to its drugs Syprine, Mephyton, Uceris, Xenazine Tabs, Vanos, and Retin-A Micro. Indeed, Valeant began marketing an authorized generic version of Glumetza in February 2017, after its No-AG pact with Lupin expired.

224. After Valeant's authorized generic entered the market, Lupin's CEO admitted that "[t]he authorized generic was a pretty tough competitor for us to have and that brought the pricing down for the entire market." Absent the unlawful No-AG Payment, the substantial price decreases attendant upon an authorized generic would have occurred sooner and simultaneously with (or before) Lupin's earlier entry into the market.

225. Defendants' unlawful MFE and MFEP compounded the No-AG Payment's anticompetitive effects. The MFE and MFEP prevented Sun and Watson from undoing the delay in generic entry caused by the No-AG Payment. Those anticompetitive clauses undermined the incentives that Congress had provided for Sun, Watson, and other potential competitors to enter the market before Lupin's unlawfully agreed February 2016 entry date. Absent the MFE and MFEP, Sun and Watson would have entered the market much sooner than they did, well before 2015. The MFE and MFEP caused Plaintiff and other Class members to incur overcharges on their purchases of both branded and generic Glumetza.

226. Defendants' anticompetitive conduct created and extended the Glumetza monopoly, resulting in its getting into the hands of Valeant. Absent Defendants' anticompetitive conduct, Lupin would have begun marketing generic Glumetza before Valeant's April 2015 acquisition of the

Glumetza monopoly, and as soon as May 2012. The mid-2015 price increases on branded Glumetza never would have occurred.

227. Absent the Defendants' unlawful conduct, Lupin would have entered the market in or about 2012, when the brand price for a 30-day supply of 1000 mg Glumetza was $250. Long before 2015, generic competition would have driven the price down to, at most, $55.

228. As a result of the delay in generic entry and the Defendants' full exploitation of the monopoly that the delay created, only the branded product was available in 2015, and the monthly price for 1000 mg Glumetza after Valeant's price increases was more than $3,000. That price was more than 50 times greater than it would have been if the Defendants had not delayed and impaired generic competition. Plaintiff and other Class members also incurred substantial overcharges from 2012 until the gigantic price increases in 2015, and they continue to incur ongoing and accumulating overcharges today.

229. Defendants' unlawful conduct also harmed Plaintiff and Class members by increasing the prices charged by Glumetza generics. When entering a market, generic manufacturers price their products based on a percentage discount off of the then-prevailing brand price. Absent the Defendants' unlawful conduct, the generics would have entered in or about 2012, when the price for a 30-day supply of 1000 mg brand Glumetza was about $250 rather than $3,000. Thus, Defendants' unlawful conduct has caused Plaintiff and Class members to pay substantial overcharges—more than a 1000% overcharge—on their purchases of Glumetza generics, beginning in February 2016 and continuing until today.

X. MARKET POWER

230. At all relevant times, Defendants had substantial market power over Glumetza and its generic equivalents. The Defendants had the power to maintain the prices of those drugs at supracompetitive levels without losing sufficient sales to other products, except for AB-rated generic versions of Glumetza, to make the supracompetitive prices unprofitable.

231. A small but significant, non-transitory increase in the price of brand Glumetza, above the competitive level, did not cause a significant loss of sales to any product other than AB-rated

versions of Glumetza. At competitive prices, brand Glumetza does not exhibit significant, positive cross-elasticity of demand with respect to price with any product or treatment for diabetes other than AB-rated generic versions of Glumetza.

232. Direct evidence of Defendants' market power includes the following: (a) absent Defendants' unlawful conduct, generic Glumetza would have entered the market much earlier at a substantial discount to brand Glumetza; (b) when generic Glumetza eventually entered the market, it quickly took a substantial portion of brand Glumetza's unit sales; (c) Defendants' gross margin on Glumetza (including the costs of ongoing research/development and marketing) at all relevant times was in excess of 70%; (d) Defendants never lost Glumetza sales or lowered the price of Glumetza to the competitive level in response to the pricing of other brand or generic drugs except AB-rated generic Glumetza; (e) from 2012 to 2015, Defendants profitably raised the price of Glumetza by more than 40%; and (f) in 2015 Defendants profitably raised the price of Glumetza by more than 750%.

233. The Defendants' power to profitably raise these prices above the competitive level results in substantial part from a significant imperfection in the United States marketplace for prescription pharmaceuticals. Branded drug manufacturers can exploit this imperfection in order to obtain or maintain market power.

234. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the product choice and the payment obligation, the product's price plays an appropriate role in the person's choice and, consequently, manufacturers have an appropriate incentive to reduce their prices to the competitive level.

235. The pharmaceutical marketplace is characterized by a "disconnect" between product selection and the payment obligation. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Glumetza, to patients without a prescription. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient's doctor chooses which product the patient will buy, while the patient (and in most cases his or her insurer) has the obligation to pay for it.

236. Brand manufacturers, including Santarus, Salix, and Valeant, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware, are largely insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

237. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced price elasticity, in turn, gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as market power. The result of these pharmaceutical market imperfections and marketing practices is that brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including Glumetza.

238. During the relevant time, Defendants had monopoly power in the market for Glumetza and AB-rated generic substitutes because they had the power to exclude competition and/or raise or maintain the price of Glumetza to supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

239. The existence of other branded diabetes drug products did not constrain the price of Glumetza to the competitive level. Defendants needed to control only Glumetza and its AB-rated generic equivalents, and no other products, in order to maintain the price of Glumetza at supracompetitive prices. Only the market entry of a competing, AB-rated version of Glumetza could prevent Defendants from profitably maintaining prices at supracompetitive levels.

240. Brand Glumetza is therapeutically differentiated from all diabetes products other than AB-rated generic versions of Glumetza.

241. In general, metformin is considered the first-choice medication for the treatment of Type 2 diabetes and is not reasonably interchangeable with other Type 2 diabetes drugs. In part, this

is the result of metformin's long-term safety profile, which is not available for many newer Type 2 diabetes drugs such as DPP-4 inhibitors. Metformin also has better cardiovascular mortality than sulfonylurea drugs used to treat Type 2 diabetes. Metformin is also considered weight neutral or helps people lose weight.

242. Glumetza is not therapeutically interchangeable with metformin products that are unavailable in an extended-release form. Metformin can cause gastrointestinal side effects, which can be reduced by taking an extended-release form. Additionally, extended-release forms of metformin can reduce the daily dosing to a single once-a-day pill providing a simpler dosing regimen. The differing efficacy, dosing, safety and side-effect profiles of different oral Type 2 diabetes drugs play a critical role in doctors' selection of the most appropriate form of the drug for each patient, and a patient's compliance with taking an oral Type 2 diabetes drug is improved with one that requires fewer doses and that the patient can better tolerate.

243. Glumetza is also not reasonably interchangeable with other extended-release forms of metformin such as Glucophage XR and Fortamet. This non-interchangeability arises from, among other reasons, the way that different patients react to the products' varying release mechanisms.

244. Specifically, a substantial number of doctors perceive Glumetza to offer the possibility of reduced gastrointestinal side effects for patients, compared to other extended-release metformin products. Glumetza uses a polymer delivery technology that expands from stomach fluid, preventing the pill from moving into the intestine. The stomach fluid then dissolves and releases the metformin over a period of 8 to 10 hours. The dissolved metformin is thus mixed, over time, with other contents of the patient's stomach and transported into the duodenum, where it is absorbed.

245. This process results in some substantial number of doctors concluding that Glumetza may cause fewer gastrointestinal side effects than other extended-release metformin products. Assertio/Santarus, Salix, and Valeant differentiated Glumetza from extended-release metformin products in their marketing, on the ground that it retains metformin in the patient's stomach, allowing for constant multi-hour flow of the drug into the gastrointestinal tract. And they asserted that this technology offered patients a significantly enhanced opportunity for increased absorption of the drug. They touted to investors and others that "physicians are receptive to Glumetza's

differentiating features of controlled delivery and GI tolerability." Moreover, the extended-release mechanism dissolves at the end of its useful life and is passed through the gastrointestinal tract and eliminated.

246. In contrast, for example, another extended-release metformin prescription drug—Fortamet—delivers metformin throughout the entire gastrointestinal tract. Fortamet tablets have a membrane surrounding the metformin, and the membrane has two laser-drilled holes. Water is taken into the holes and dissolves the metformin inside, and the dissolved drug is released through those holes at a constant rate all the time that the pill is moving through the small intestine. Some substantial number of doctors conclude, therefore, that Fortamet has a higher likelihood of causing gastrointestinal side effects. And patients typically will see the pill's shell in their stool.

247. Very substantial decreases in the price of other extended-release metformin products did not constrain the price of brand Glumetza to the competitive level. For example, generic Fortamet entered the market in 2012, substantially driving down the average price of a Fortamet pill (weighted average of brand and generic price). Despite that substantial price decrease, from 2012 to mid-2015 the quarterly unit sales of Glumetza *increased* while the *price increased more than 40%.* The percentage increase in Glumetza net revenue (net of all discounts, rebates, etc.) was at least that great.

248. A generic version of another extended-release metformin product—Glucophage XR—has been available since 2005. That product's extended-release mechanism is similar to Fortamet's and dissimilar to Glumetza's. Yet from 2012 through mid-2015 Glumetza had the sales, price, and net revenue gains described above.

249. Neither Glucophage XR (brand or generic) nor Fortamet (brand or generic) prevented the nearly 800% price increase in Glumetza in 2015. That price increase was enormously profitable for Valeant. The dollar sales of brand Glumetza for the third and fourth quarters of 2015 (after the price increase but before Lupin's entry) were more than $800 million; the sales in the prior two quarters were less than $145 million.

250. To the extent that Plaintiff is required to prove market power through circumstantial evidence by first defining a relevant product market, Plaintiff alleges that the relevant antitrust market is the market for Glumetza and its AB-rated generic equivalents.

251. At all relevant times, the Defendants were protected by high barriers to entry due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and state statutes that require prescriptions for the purchase of the products at issue and restrict substitution of those products at the pharmacy counter. The products in these markets require significant investments of time and money to design, develop, and distribute. In addition, the markets require government approvals to enter and/or may assertedly be covered by patents or other forms of intellectual property. Defendants' unlawful conduct further restricted entry. Thus, during the relevant time, existing and potential market entrants lacked the ability to enter the market and/or expand output quickly in the short run in response to Defendants' higher prices or reduced output.

252. The relevant geographic market is the United States and its territories. Defendants Assertio, Santarus, and Valeant's market share in the relevant market was 100% until Lupin's entry in 2016.

XI. EFFECT ON INTERSTATE COMMERCE

253. During the relevant time period, Defendants manufactured, sold, and shipped Glumetza and generic Glumetza across state lines in an uninterrupted flow of interstate commerce.

254. During the relevant time period, Plaintiff and Class members purchased substantial amounts of Glumetza and/or generic Glumetza directly from Defendants. As a result of Defendants' illegal conduct, Plaintiff and Class members were compelled to pay, and did pay, artificially inflated prices for Glumetza and generic Glumetza.

255. During the relevant time period, Defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All Defendants engaged in illegal activities, as charged in herein, within the flow of, and substantially affecting, interstate commerce, including in this district.

XII. CLASS ACTION ALLEGATIONS

256. Plaintiff brings this action on behalf of itself and, under Federal Rules of Civil Procedure 23(a) and 23(b)(2) and (b)(3), as representative of a Class defined as:

> All persons or entities in the United States and its territories who directly purchased Glumetza or generic Glumetza from a Defendant from May 6, 2012 until the effects of Defendants' conduct cease (the "Class").

257. Excluded from the Class are Defendants and any of their officers, directors, management, employees, subsidiaries, and affiliates.

258. Also excluded from the Class are the government of the United States and all agencies thereof, and all state or local governments and all agencies thereof.

259. Members of the Class are so numerous and geographically dispersed that joinder of all members is impracticable. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The Class is readily identifiable from information and records in Defendants' possession.

260. Plaintiff's claims are typical of those of the Class members. Plaintiff and all Class members were damaged by the same wrongful conduct of the Defendants—*i.e.*, as a result of Defendants' conduct, Class members paid artificially inflated prices for Glumetza and AB-rated generic equivalents.

261. Plaintiff will fairly and adequately protect and represent the Class's interests. The Plaintiff's interests are coincident with, and not antagonistic to, those of the other Class members.

262. Counsel who represent Plaintiff are experienced in the prosecution of class action antitrust litigation and have particular experience with class action antitrust litigation involving pharmaceutical products.

263. Questions of law and fact common to the Class members predominate over questions that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

264. Questions of law and fact common to the Class include:

a. Whether the Defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;

b. Whether there exist any legitimate procompetitive reasons for some or all of the Defendants' conduct;

c. To the extent any such procompetitive benefits exist, whether there were less restrictive means of achieving them;

d. Whether direct proof of the Defendants' monopoly power is available and, if so, whether it is sufficient to prove the Defendants' monopoly power without the need to define the relevant market;

e. Whether the Defendants' scheme, in whole or in part, has substantially affected interstate commerce;

f. Whether the Defendants' scheme, in whole or in part, caused antitrust injury through overcharges to the business or property of the Plaintiff and the Class members;

g. Whether Defendants conspired to delay generic competition for Glumetza;

h. Whether, pursuant to the No-AG pact, Assertio/Santarus, Salix, and Valeant's promise not to compete against Lupin's generic product constituted a large and unjustified payment;

i. Whether Defendants' No-AG Payment was necessary to yield some cognizable, non-pretextual procompetitive benefit;

j. Whether the No-AG Payment, MFE, and/or MFEP caused Sun, Watson, and/or other generic manufacturers to delay entry into the market;

k. Whether the MFE and MFEP were necessary to yield some cognizable, non-pretextual procompetitive benefit;

l. Whether Defendants' conduct created a bottleneck to further delay generic competition for Lupin;

m. Whether Defendants' conduct harmed competition;

n. Whether Defendants possessed the ability to control prices and/or exclude competition for Glumetza;

o. Whether Defendants' unlawful conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Glumetza; and

p. The quantum of overcharges paid by the Class in the aggregate.

265. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The

benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that they could not practicably pursue individually, substantially outweigh potential difficulties in management of this class action.

266. Defendants' anticompetitive conduct has imposed, and unless Plaintiff obtains equitable relief will continue to impose, a common antitrust injury on Plaintiff and all Class members. Defendants' anticompetitive conduct and their relationships with the Class members have been substantially uniform. Defendants have acted and refused to act on grounds that apply generally to the Class, and injunctive and other equitable relief is appropriate respecting the Class as a whole.

267. Plaintiff know of no special difficulty to be encountered in litigating this action that would preclude its maintenance as a class action.

XIII. DEFENDANTS CONCEALED THEIR UNLAWFUL AGREEMENTS

268. A cause of action accrued for Plaintiff each time a brand or generic Glumetza product was sold to Plaintiff at a supracompetitive price made possible by Defendants' anticompetitive conduct. And each sale of brand or generic Glumetza at a supracompetitive price constituted another overt act in furtherance of Defendants' continuing anticompetitive scheme. Other overt acts in furtherance of Defendants' continuing conspiracy include, but are not limited to, Lupin's refraining from entering the market until February 2016 and Valeant's refraining from marketing an authorized generic Glumetza until February 2017. Accordingly, Plaintiff is entitled to recover all damages on all branded and generic Glumetza sales made to Plaintiff at supracompetitive prices within four years of the filing of this lawsuit.

269. Due to Defendants' fraudulent concealment of their unlawful conduct, however, Plaintiff and Class members are entitled to recover damages reaching back even beyond four years before the filing of this Complaint. Plaintiff and Class members had no knowledge of Defendants' unlawful self-concealing scheme and could not have discovered the scheme and conspiracy through the exercise of reasonable diligence more than four years before the filing of this Complaint.

270. Defendants' scheme was self-concealing, and Defendants employed deceptive tactics and techniques of secrecy to avoid detection of, and to fraudulently conceal, their contract, combination, conspiracy, and scheme.

271. Defendants wrongfully and affirmatively concealed the existence of their ongoing combination and conspiracy from Plaintiff and Class members. Defendants repeatedly made public reference to Lupin's agreement to delay entry until February 2016, but consistently, consciously, and actively omitted the fact that Lupin had agreed to that delayed date in exchange for a No-AG Payment. For example:

a. In a May 8, 2012 filing with the Securities and Exchange Commission ("SEC"), Assertio included a redacted copy of its settlement agreement with Lupin. Assertio redacted all references to the No-AG Payment. Based solely on information received and events occurring within the last four years, Plaintiff now believes that the redacted agreement refers to the No-AG Payment as follows:

> "Section 3.5. [***]
>
> Section 3.6. [***] Notwithstanding the provisions of Sections 3.4 and 3.5, Depomed and Santarus shall have the right to: [***]"

b. On March 27, 2012, pursuant to their settlement Assertio and Lupin asked this Court to enter a consented-to injunction in the patent litigation. Those Defendants falsely represented to this Court—and placed on the public record—that the terms of their settlement were in "good faith," "serve the public interest," were "procompetitive," and "benefit … the parties and consumers alike." Consent Injunction and Dismissal Order, *Depomed, Inc. v. Lupin Pharmaceuticals*, *Inc., et al.,* No. 4:09-cv-05587-PJH, ECF No. 152, at p. 1 (March 27, 2012). Those Defendants affirmatively advised the Court and the public of the agreed entry date of February 1, 2016 but omitted all references to the No-AG Payment. *See id*. at 5(a).

c. In the following SEC filings Santarus affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Payment: Santarus Inc., Annual Report (Form 10-K), at 24 (March 5, 2012); Santarus Inc., Quarterly Report (Form 10-Q), at 12 (May 5, 2012); Santarus Inc., Quarterly Report (Form 10-Q), at 12 (August 7, 2012); Santarus Inc., Quarterly Report (Form 10-Q), at 12 (November 8, 2012); Santarus Inc., Quarterly Report (Form 10-Q), at 34 (November 7, 2013); Santarus Inc., Quarterly Report (Form 10-Q), at 13 (May 6, 2013); Santarus Inc., Quarterly Report (Form 10-Q), at 14 (August 6, 2013).

d. In the following SEC filings Salix affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Payment: Salix, Pharmaceuticals, Ltd., Annual Report (Form 10-K), at 9 (March 1, 2013); Salix, Pharmaceuticals, Ltd., Annual Report (Form 10-K), at 7 (February 28, 2014).

e. In addition to the May 8, 2012 SEC filing discussed above, in the following SEC filings Assertio (formerly known as Depomed, Inc.) affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Payment: Depomed Inc., Annual Report (Form 10-K), at 5 (March 8, 2012); Depomed Inc.,

Quarterly Report (Form 10-Q), at 22 (August 3, 2012); Depomed Inc., Quarterly Report (Form 10-Q), at 24 (November 5, 2012); Depomed Inc., Quarterly Report (Form 10-Q), at 21 (November 9, 2013); Depomed Inc., Quarterly Report (Form 10-Q), at 21 (August 8, 2013); Depomed Inc., Quarterly Report (Form 10-Q), at 23 (November 7, 2013).

f. In a call with stock analysts on May 8, 2012 Assertio affirmatively referred to the agreed February 2016 entry date but omitted all references to the No-AG Payment.

g. In a press release dated May 8, 2012 Santarus affirmatively referred to the agreed February 2016 entry date but omitted all references to the No-AG Payment.

h. In calls with stock analysts on November 7, 2013 and January 16, 2014, Salix affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Payment.

i. In a call with stock analysts on October 27, 2015 Lupin affirmatively referred to the agreed February 2016 entry date but omitted all references to the No-AG Payment.

272. The Defendants did not publicly disclose the No-AG Payment until doing so suited their interests. Specifically, Lupin was trying in a February 5, 2016 call with stock analysts to pump up the value of its stock. To emphasize that it would make extraordinary profits on the sale of generic Glumetza, Lupin revealed publicly for the first time that the settlement agreement included a No-AG pact. Plaintiff has filed this Complaint within four years of that first public revelation of the No-AG Payment.

273. Because the scheme and conspiracy were both self-concealing and affirmatively concealed by Defendants, Plaintiff and Class members had no knowledge of the scheme and conspiracy more than four years before the filing of this Complaint; they did not have the facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed; and if they would have had the facts or information to cause them to conduct an investigation, any such investigation would not have revealed the existence of Defendants' unlawful conspiracy.

274. Plaintiff and Class members lacked the facts and information necessary to form a good faith basis for believing that any legal violations had occurred. Reasonable diligence on the part of Plaintiff and Class members would not have uncovered those facts more than four years before the filing of this complaint.

275. The partially redacted settlement agreement that Assertio included in its May 8, 2012 SEC filing revealed the existence of an MFE. It also revealed an outline of what may be the MFEP but did not include the MFEP's essential terms. Plaintiff learned of the MFEP's essential terms, and in the exercise of reasonable diligence could have learned of them, only through information gained and events occurring within the last four years.

276. Plaintiff does not allege that the MFE or MFEP, alone or together with each other, is unlawful. As alleged in detail above, the MFE and MFEP prevented later filers from unraveling the anticompetitive effects of the No-AG Payment. That is, Plaintiff alleges that the MFE and MFEP are anticompetitive in the context of an unlawful conspiracy of which the No-AG Payment is the centerpiece. Plaintiff became aware of that context, and in the exercise of reasonable diligence could have become aware of it, only after learning of the existence of the No-AG Payment.

277. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting Plaintiff's and Class members' claims have been tolled.

XIV. CLAIMS FOR RELIEF

COUNT ONE
VIOLATION OF 15 U.S.C. § 1
(AGAINST ALL DEFENDANTS)

278. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

279. Defendants violated 15 U.S.C. § 1 by entering into and/or furthering an unreasonable restraint of trade, defined as Assertio/Santarus, Salix, and Valeant's agreement with Lupin, and adherence to that agreement, to make a reverse payment—the No-AG Payment—in exchange for Lupin's delaying its generic Glumetza until February 1, 2016, and to allocate the market for branded and generic Glumetza.

280. At all relevant times, Defendants individually and/or collectively had substantial market power with respect to sales of Glumetza and its AB-rated generic equivalents in the United States.

281. On or about February 22, 2012, Defendants entered into a reverse payment agreement, a continuing illegal contract, combination, and restraint of trade under which Assertio/Santarus, Salix, and Valeant agreed to pay, and paid, Lupin substantial consideration in exchange for Lupin's agreement to delay bringing its generic version of Glumetza to the market, the purpose and effect of which was to: (a) delay generic entry of Glumetza in order to lengthen the period in which brand Glumetza would make supracompetitive profits; (b) keep an authorized generic off the market during Lupin's 180-day ANDA Exclusivity period, or longer, thereby allowing Lupin to charge supracompetitive prices and make supracompetitive profits on sales of generic Glumetza; (c) delay the date that other generic manufacturers would enter the market; and (d) raise and maintain the prices that Plaintiff and other Class members would pay for Glumetza and its AB-rated equivalents at supracompetitive levels.

282. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraint. Even if there were some conceivable and cognizable justification, the No-AG Payment was not necessary to achieve such a purpose, and, in any event, such procompetitive effects would be outweighed by the restraint's anticompetitive effects on direct purchasers, competition, and consumers.

283. As a direct result of Defendants' violation of 15 U.S.C. § 1, Plaintiff and other Class members have been injured, and unless Plaintiff obtains equitable relief will continue to be injured, in their business or property. Plaintiff's and Class members' injury consists of having paid higher prices for their Glumetza requirements, and continuing to pay higher prices, than they would have paid in the absence of the violation. Such injury, called "overcharges," is of the type the antitrust laws were designed to prevent, and flows from that which makes Defendants' conduct unlawful. Plaintiff is the proper entity to bring a case concerning this conduct.

COUNT TWO
VIOLATION OF 15 U.S.C. § 2
(AGAINST ALL DEFENDANTS)

284. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

285. Defendants violated 15 U.S.C. § 2 by monopolizing and conspiring to monopolize the market for Glumetza and its AB-rated equivalents in the United States.

286. At all relevant times, Defendants possessed substantial market power (*i.e.*, monopoly power) with respect to Glumetza and its AB-rated equivalents. Defendants possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

287. That market power is coupled with strong regulatory and contractual barriers to entry into the market.

288. As alleged extensively above, Defendants willfully maintained monopoly power by using restrictive or exclusionary conduct, rather than using greater business acumen, and injured Plaintiff and the Class thereby.

289. Defendants' conscious objective was to further their dominance through exclusionary conduct.

290. As stated more fully above, Defendants knowingly, willfully, and wrongfully maintained monopoly power and harmed competition by:

- Entering into and abiding by the No-AG pact; and
- Entering into and abiding by the MFE and MFEP.

291. Defendants' anticompetitive conduct is exclusionary conduct the purpose and effect of which is to willfully maintain monopoly power, which harms purchasers, the competitive process, and consumers, in violation of Section 2 of the Sherman Act.

292. To the extent that Defendants are permitted to assert one, there is and was no cognizable, non-pretextual, procompetitive justification for their exclusionary conduct that outweighs its harmful effects. Even if there were some conceivable justification that Defendants were permitted to assert, the conduct is and was broader than necessary to achieve such a purpose.

293. Plaintiff and the Class have been injured, and unless Plaintiff obtains equitable relief will continue to be injured, in their business and property as a result of Defendants' continuing monopolization in violation of Section 2 of the Sherman Act.

XV. DEMAND FOR JUDGMENT

294. WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, respectfully demand that this Court:

a. Determine that this action may be maintained as a class action pursuant to Rules 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Class, and declare Plaintiff as the representative of the Class;

b. Enter joint and several judgments against Defendants and in favor of Plaintiff and the Class;

c. Award the Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

d. Grant permanent injunctive relief pursuant to Section 16 of the Clayton Act to remedy the ongoing anticompetitive effects of Defendants' unlawful conduct;

e. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

f. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XVI. JURY DEMAND

295. Pursuant to Fed. Civ. P. 38, Plaintiff on behalf of itself and the proposed Class demand a trial by jury on all issues so triable.

Dated: October 21, 2019

By______________________________
A.J. de Bartolomeo

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